CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-896

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

Department of Health and Human Services
Food and Drug Administration

PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use

Form Approved: OMB No. 0910-0513
Expiration Date: 07/31/06
See OMB Statement on Page 3.

NDA NUMBER
21-896

NAME OF APPLICANT / NDA HOLDER
Gilead Sciences, Inc.

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME (OR PROPOSED TRADE NAME)
Emtriva

ACTIVE INGREDIENT(S)	STRENGTH(S)
emtricitabine	200 mg capsule 10 mg/mL oral solution

DOSAGE FORM
Capsule or oral solution

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4).
Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the only information relied upon by FDA for listing a patent in the Orange Book.

For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

or each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the rmation described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, plete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent
5,210,085	05/11/1993	05/11/2010

d. Name of Patent Owner	Address *(of Patent Owner)*	
Emory University	1784 N. Decatur Rd., Ste. 130	
	City/State Atlanta, GA	
	ZIP Code 30322	FAX Number *(if available)* (404) 727-1271
	Telephone Number (404) 727-7218	E-Mail Address *(if available)* msevers@emory.edu

e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States)	Address *(of agent or representative named in 1.e.)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*

the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? ☐ Yes ☒ No

g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? ☐ Yes ☒ No

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

	Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
2.2	Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
2.3	If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No
2.4	Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.		
2.5	Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.)	☐ Yes	☒ No
2.6	Does the patent claim only an intermediate?	☐ Yes	☒ No
2.7	If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

3. Drug Product (Composition/Formulation)

	Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
3.2	Does the patent claim only an intermediate?	☐ Yes	☒ No
3.3	If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1	Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2	Patent Claim Number *(as listed in the patent)*: 1 — Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2a	If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of emtricitabine.	

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1	Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
	Patent Claim Number *(as listed in the patent)*: 4 — Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No

4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of a β-isomer of emtricitabine.

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Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No

4.2 Patent Claim Number *(as listed in the patent)* 9	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of emtricitabine.

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No

4.2 Patent Claim Number *(as listed in the patent)* 10	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of a pharmaceutically acceptable salt of emtricitabine.

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No

4.2 Patent Claim Number *(as listed in the patent)* 11	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of the pharmaceutically acceptable salt of the β-isomer of emtricitabine.

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No

4.2 Patent Claim Number *(as listed in the patent)* 13	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No
If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of a pharmaceutically acceptable salt of emtricitabine.

4. Method of Use

Sponsors must submit the information in section 4 separately for each patent claim claiming a method of using the pending drug product for which approval is being sought. For each method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
Patent Claim Number *(as listed in the patent)*: 14 — Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection wherein emtricitabine is administered in a pharmaceutically acceptable carrier.	

4. Method of Use

Sponsors must submit the information in section 4 separately for each patent claim claiming a method of using the pending drug product for which approval is being sought. For each method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2 Patent Claim Number *(as listed in the patent)*: 15 — Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection wherein the β-isomer of emtricitabine is administered in a pharmaceutically acceptable carrier.	

4. Method of Use

Sponsors must submit the information in section 4 separately for each patent claim claiming a method of using the pending drug product for which approval is being sought. For each method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
Patent Claim Number *(as listed in the patent)*: 17 — Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of emtricitabine in a pharmaceutically acceptable carrier.	

4. Method of Use

Sponsors must submit the information in section 4 separately for each patent claim claiming a method of using the pending drug product for which approval is being sought. For each method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2 Patent Claim Number *(as listed in the patent)*: 18 — Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of a pharmaceutically acceptable salt of emtricitabine in a pharmaceutically acceptable carrier.	

4. Method of Use

Sponsors must submit the information in section 4 separately for each patent claim claiming a method of using the pending drug product for which approval is being sought. For each method of use claim referenced, provide the following information:

Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2 Patent Claim Number *(as listed in the patent)*: 19 — Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No

4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of a pharmaceutically acceptable salt of the β-isomer of emtricitabine in a pharmaceutically acceptable carrier.

Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No

4.2 Patent Claim Number *(as listed in the patent)* 21	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating a human having an HIV infection comprising administering to the human an effective HIV-treatment amount of the pharmaceutically acceptable salt of emtricitabine in a pharmaceutically acceptable carrier.

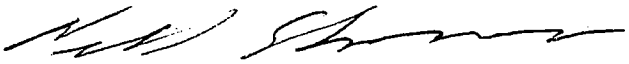
5. No Relevant Patents

For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. ☐ Yes

6. Declaration Certification

6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.***

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*	Date Signed
	03/03/2005

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☒ NDA Applicant/Holder	☐ NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name William Schmonsees	
Address Gilead Sciences, Inc. 333 Lakeside Dr.	City/State Foster City, CA
ZIP Code 94404	Telephone Number (650) 522-5525
FAX Number *(if available)* (650) 522-5575	E-Mail Address *(if available)* wschmonsees@gilead.com

Department of Health and Human Services
Food and Drug Administration

PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use

Form Approved: OMB No. 0910-0513
Expiration Date: 07/31/06
See OMB Statement on Page 3.

NDA NUMBER
21-896

NAME OF APPLICANT / NDA HOLDER
Gilead Sciences, Inc.

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME (OR PROPOSED TRADE NAME)
Emtriva

ACTIVE INGREDIENT(S)	STRENGTH(S)
emtricitabine	200 mg capsule 10 mg/mL oral solution

DOSAGE FORM
Capsule or oral solution

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4).
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each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the rmation described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, nplete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent
5,814,639	9/29/1998	09/29/2015

d. Name of Patent Owner	Address *(of Patent Owner)*	
Emory University	1784 N. Decatur Rd., Ste. 130	
	City/State: Atlanta, GA	
	ZIP Code: 30322	FAX Number *(if available)*: (404) 727-1271
	Telephone Number: (404) 727-7218	E-Mail Address *(if available)*: msevers@emory.edu

e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States)	Address *(of agent or representative named in 1.e.)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*

f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? ☐ Yes ☒ No

g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? ☐ Yes ☒ No

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

2.1	Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
2.2	Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
2.3	If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No
2.4	Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.		
2.5	Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.)	☐ Yes	☒ No
2.6	Does the patent claim only an intermediate?	☐ Yes	☒ No
2.7	If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

3. Drug Product (Composition/Formulation)

	Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
3.2	Does the patent claim only an intermediate?	☐ Yes	☒ No
3.3	If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1	Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
4.2	Patent Claim Number *(as listed in the patent)*	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☐ Yes ☐ No	
4.2a	If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)*	

5. No Relevant Patents

	For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in anufacture, use, or sale of the drug product.	☐ Yes

6. Declaration Certification

6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.***

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6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*	Date Signed
	03/03/2005

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☒ NDA Applicant/Holder	☐ NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name William Schmonsees	
Address Gilead Sciences, Inc. 333 Lakeside Dr.	City/State Foster City, CA
ZIP Code 94404	Telephone Number (650) 522-5525
FAX Number *(if available)* (650) 522-5575	E-Mail Address *(if available)* wschmonsees@gilead.com

Department of Health and Human Services
Food and Drug Administration

PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT

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1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent
5,914,331	06/22/1999	09/29/2015

d. Name of Patent Owner	Address *(of Patent Owner)*	
Emory University	1784 N. Decatur Rd., Ste. 130	
	City/State: Atlanta, GA	
	ZIP Code: 30322	FAX Number *(if available)*: (404) 727-1271
	Telephone Number: (404) 727-7218	E-Mail Address *(if available)*: msevers@emory.edu

e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States)	Address *(of agent or representative named in 1.e.)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*

f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? ☐ Yes ☒ No

g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? ☐ Yes ☒ No

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

2.1	Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
2.2	Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
2.3	If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No
2.4	Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.		
2.5	Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.)	☐ Yes	☒ No
2.6	Does the patent claim only an intermediate?	☐ Yes	☒ No
2.7	If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

3. Drug Product (Composition/Formulation)

3.1	Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
3.2	Does the patent claim only an intermediate?	☐ Yes	☒ No
3.3	If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1	Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
4.2	Patent Claim Number *(as listed in the patent)*	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☐ Yes ☐ No	
4.2a	If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)*	

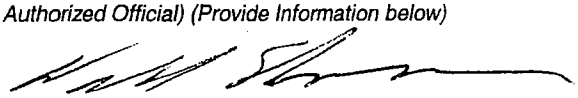
5. No Relevant Patents

	For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in manufacture, use, or sale of the drug product.	☐ Yes

6. Declaration Certification

6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.***

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*	Date Signed
	03/03/2005

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☒ NDA Applicant/Holder	☐ NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name William Schmonsees	
Address Gilead Sciences, Inc. 333 Lakeside Dr.	City/State Foster City, CA
ZIP Code 94404	Telephone Number (650) 522-5525
FAX Number *(if available)* (650) 522-5575	E-Mail Address *(if available)* wschmonsees@gilead.com

Department of Health and Human Services
Food and Drug Administration

PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use

Form Approved: OMB No. 0910-0513
Expiration Date: 07/31/06
See OMB Statement on Page 3.

NDA NUMBER
21-896

NAME OF APPLICANT / NDA HOLDER
Gilead Sciences, Inc.

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME (OR PROPOSED TRADE NAME)
Emtriva

ACTIVE INGREDIENT(S)	STRENGTH(S)
emtricitabine	200 mg capsule 10 mg/mL oral solution

DOSAGE FORM
Capsule or oral solution

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4).
Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the only information relied upon by FDA for listing a patent in the Orange Book.

For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent
6,642,245 B1	11/4/2003	11/4/2020

d. Name of Patent Owner	Address *(of Patent Owner)*	
Emory University	1784 N. Decatur Rd., Ste. 130	
	City/State Atlanta, GA	
	ZIP Code 30322	FAX Number *(if available)* (404) 727-1271
	Telephone Number (404) 727-7218	E-Mail Address *(if available)* msevers@emory.edu

e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States) ☞	Address *(of agent or representative named in 1.e.)*	
	City/State	
	ZIP Code	FAX Number *(if available)*
	Telephone Number	E-Mail Address *(if available)*

f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? ☐ Yes ☒ No

g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? ☐ Yes ☒ No

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

2.1	Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
2.2	Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
2.3	If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No
2.4	Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.		
2.5	Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.)	☐ Yes	☒ No
2.6	Does the patent claim only an intermediate?	☐ Yes	☒ No
2.7	If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

3. Drug Product (Composition/Formulation)

3.1	Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
3.2	Does the patent claim only an intermediate?	☐ Yes	☒ No
3.3	If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1	Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2	Patent Claim Number *(as listed in the patent)*: 1 — Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2a	If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating HIVinfection in humans comprising administering an effective amount of emtricitabine in a pharmaceutically acceptable carrier.	

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1	Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
4.2	Patent Claim Number *(as listed in the patent)*: 2 — Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement?	☒ Yes	☐ No

4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating HIV infection in humans comprising administering an effective amount of emtricitabine in a carrier suitable for oral delivery.

Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No

4.2 Patent Claim Number *(as listed in the patent)* 3	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating HIVinfection in humans comprising administering an effective amount of emtricitabine wherein the carrier comprises a capsule.

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No

4.2 Patent Claim Number *(as listed in the patent)* 6	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating HIVinfection in humans comprising administering an effective amount of emtricitabine that is at least 95% free of its corresponding β-D-enantiomer.

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1 Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No

4.2 Patent Claim Number *(as listed in the patent)* 8	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☒ Yes ☐ No
4.2a If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)* A method for treating HIVinfection in humans comprising administering an effective amount of emtricitabine as an isolated enantiomer.

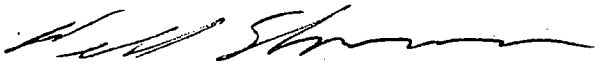
5. No Relevant Patents

For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. ☐ Yes

6. Declaration Certification

6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.***

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*	Date Signed
	07/03/2005

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☒ NDA Applicant/Holder	☐ NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name William Schmonsees	
Address Gilead Sciences, Inc. 333 Lakeside Dr.	City/State Foster City, CA
ZIP Code 94404	Telephone Number (650) 522-5525
FAX Number *(if available)* (650) 522-5575	E-Mail Address *(if available)* wschmonsees@gilead.com

Department of Health and Human Services
Food and Drug Administration

PATENT INFORMATION SUBMITTED WITH THE FILING OF AN NDA, AMENDMENT, OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation and Composition) and/or Method of Use

Form Approved: OMB No. 0910-0513
Expiration Date: 07/31/06
See OMB Statement on Page 3.

NDA NUMBER
21-896

NAME OF APPLICANT / NDA HOLDER
Gilead Sciences, Inc.

The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act.

TRADE NAME (OR PROPOSED TRADE NAME)
Emtriva

ACTIVE INGREDIENT(S)	STRENGTH(S)
emtricitabine	200 mg capsule 10 mg/mL oral solution

DOSAGE FORM
Capsule or oral solution

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) with an NDA application, amendment, or supplement as required by 21 CFR 314.53 at the address provided in 21 CFR 314.53(d)(4).
Within thirty (30) days after approval of an NDA or supplement, or within thirty (30) days of issuance of a new patent, a new patent declaration must be submitted pursuant to 21 CFR 314.53(c)(2)(ii) with all of the required information based on the approved NDA or supplement. The information submitted in the declaration form submitted upon or after approval will be the only information relied upon by FDA for listing a patent in the Orange Book.

For hand-written or typewriter versions (only) of this report: If additional space is required for any narrative answer (i.e., one that does not require a "Yes" or "No" response), please attach an additional page referencing the question number.

FDA will not list patent information if you file an incomplete patent declaration or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the pending NDA, amendment, or supplement referenced above, you must submit all the information described below. If you are not submitting any patents for this pending NDA, amendment, or supplement, complete above section and sections 5 and 6.

1. GENERAL

a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent
6,703,396 B1	03/09/2004	03/09/2021

d. Name of Patent Owner	Address *(of Patent Owner)*	FAX Number *(if available)*
Emory University	1784 N. Decatur Rd., Ste. 130	(404) 727-1271
	City/State: Atlanta, GA	
	ZIP Code: 30322	
	Telephone Number: (404) 727-7218	E-Mail Address *(if available)*: msevers@emory.edu

e. Name of agent or representative who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA applicant/holder does not reside or have a place of business within the United States)	Address *(of agent or representative named in 1.e.)*	FAX Number *(if available)*
	City/State	
	ZIP Code	
	Telephone Number	E-Mail Address *(if available)*

f. Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above? ☐ Yes ☒ No

g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? ☐ Yes ☒ No

For the patent referenced above, provide the following information on the drug substance, drug product and/or method of use that is the subject of the pending NDA, amendment, or supplement.

2. Drug Substance (Active Ingredient)

2.1	Does the patent claim the drug substance that is the active ingredient in the drug product described in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
2.2	Does the patent claim a drug substance that is a different polymorph of the active ingredient described in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
2.3	If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No
2.4	Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.		
2.5	Does the patent claim only a metabolite of the active ingredient pending in the NDA or supplement? (Complete the information in section 4 below if the patent claims a pending method of using the pending drug product to administer the metabolite.)	☐ Yes	☒ No
2.6	Does the patent claim only an intermediate?	☐ Yes	☒ No
2.7	If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

3. Drug Product (Composition/Formulation)

	Does the patent claim the drug product, as defined in 21 CFR 314.3, in the pending NDA, amendment, or supplement?	☒ Yes	☐ No
3.2	Does the patent claim only an intermediate?	☐ Yes	☒ No
3.3	If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel? (An answer is required only if the patent is a product-by-process patent.)	☐ Yes	☐ No

4. Method of Use

Sponsors must submit the information in section 4 separately for* each *patent claim claiming a method of using the pending drug product for which approval is being sought. For* each *method of use claim referenced, provide the following information:

4.1	Does the patent claim one or more methods of use for which approval is being sought in the pending NDA, amendment, or supplement?	☐ Yes	☒ No
4.2	Patent Claim Number *(as listed in the patent)*	Does the patent claim referenced in **4.2** claim a pending method of use for which approval is being sought in the pending NDA, amendment, or supplement? ☐ Yes ☐ No	
4.2a	If the answer to **4.2** is "Yes," identify with specificity the use with reference to the proposed labeling for the drug product.	Use: *(Submit indication or method of use information as identified specifically in the approved labeling.)*	

› Relevant Patents

For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product. ☐ Yes

Declaration Certification

6.1 ***The undersigned declares that this is an accurate and complete submission of patent information for the NDA, amendment, or supplement pending under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.***

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Applicant/Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*

Date Signed: 03/03/2005

NOTE: Only an NDA applicant/holder may submit this declaration directly to the FDA. A patent owner who is not the NDA applicant/holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☒ NDA Applicant/Holder	☐ NDA Applicant's/Holder's Attorney, Agent (Representative) or other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name
William Schmonsees

Address Gilead Sciences, Inc. 333 Lakeside Dr.	City/State Foster City, CA
ZIP Code 94404	Telephone Number (650) 522-5525
FAX Number *(if available)* (650) 522-5575	E-Mail Address *(if available)* wschmonsees@gilead.com

EXCLUSIVITY SUMMARY

NDA # 21-896 SUPPL # HFD # 530

Trade Name EMTRIVA Oral Solution

Generic Name emtricitabine

Applicant Name Gilead Sciences, Inc

Approval Date, If Known September 27, 2005

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, and all efficacy supplements. Complete PARTS II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

a) Is it a 505(b)(1), 505(b)(2) or efficacy supplement?

YES ☒ NO ☐

If yes, what type? Specify 505(b)(1), 505(b)(2), SE1, SE2, SE3,SE4, SE5, SE6, SE7, SE8

505(b)(1)

c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

YES ☒ NO ☐

If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

d) Did the applicant request exclusivity?

YES ☒ NO ☐

If the answer to (d) is "yes," how many years of exclusivity did the applicant request?

five years

e) Has pediatric exclusivity been granted for this Active Moiety?

YES ☐ NO ☒

If the answer to the above question in YES, is this approval a result of the studies submitted in response to the Pediatric Written Request?

IF YOU HAVE ANSWERED "NO" TO ALL OF THE ABOVE QUESTIONS, GO DIRECTLY TO THE SIGNATURE BLOCKS AT THE END OF THIS DOCUMENT.

2. Is this drug product or indication a DESI upgrade?

YES ☐ NO ☒

IF THE ANSWER TO QUESTION 2 IS "YES," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8 (even if a study was required for the upgrade).

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2 as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES ☒ NO ☐

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA# 21-500 EMTRIVA (emtricitabine) 200mg Capsules

NDA#

NDA#

2. Combination product.

If the product contains more than one active moiety(as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES ☐ NO ☐

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA#

NDA#

NDA#

IF THE ANSWER TO QUESTION 1 OR 2 UNDER PART II IS "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8. (Caution: The questions in part II of the summary should only be answered "NO" for original approvals of new molecular entities.)
IF "YES," GO TO PART III.

PART III THREE-YEAR EXCLUSIVITY FOR NDAs AND SUPPLEMENTS

To qualify for three years of exclusivity, an application or supplement must contain "reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant." This section should be completed only if the answer to PART II, Question 1 or 2 was "yes."

1. Does the application contain reports of clinical investigations? (The Agency interprets "clinical investigations" to mean investigations conducted on humans other than bioavailability studies.) If the application contains clinical investigations only by virtue of a right of reference to clinical investigations in another application, answer "yes," then skip to question 3(a). If the answer to 3(a) is "yes" for any investigation referred to in another application, do not complete remainder of

summary for that investigation.

YES ☒ NO ☐

IF "NO," GO DIRECTLY TO THE SIGNATURE BLOCKS ON PAGE 8.

2. A clinical investigation is "essential to the approval" if the Agency could not have approved the application or supplement without relying on that investigation. Thus, the investigation is not essential to the approval if 1) no clinical investigation is necessary to support the supplement or application in light of previously approved applications (i.e., information other than clinical trials, such as bioavailability data, would be sufficient to provide a basis for approval as an ANDA or 505(b)(2) application because of what is already known about a previously approved product), or 2) there are published reports of studies (other than those conducted or sponsored by the applicant) or other publicly available data that independently would have been sufficient to support approval of the application, without reference to the clinical investigation submitted in the application.

(a) In light of previously approved applications, is a clinical investigation (either conducted by the applicant or available from some other source, including the published literature) necessary to support approval of the application or supplement?

YES ☒ NO ☐

If "no," state the basis for your conclusion that a clinical trial is not necessary for approval AND GO DIRECTLY TO SIGNATURE BLOCK ON PAGE 8:

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES ☒ NO ☐

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES ☐ NO ☒

If yes, explain:

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES ☐ NO ☒

If yes, explain:

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

FTC-203 - "Open-label, non-randomized trial to evaluate the safety, PK, and anti-HIV activity of FTC (given once daily) in combination with other antiretroviral (ART) agents" FTC-202 (PACTG-1021) - "Open-label, non-randomized trial to evaluate the safety/tolerability anti-HIV activity and PK of FTC when combined with didanosine (ddI) and efavirenz (EFV) in a fully QD regimen"

Studies comparing two products with the same ingredient(s) are considered to be bioavailability studies for the purpose of this section.

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

a) For each investigation identified as "essential to the approval," has the investigation been relied on by the agency to demonstrate the effectiveness of a previously approved drug product? (If the investigation was relied on only to support the safety of a previously approved drug, answer "no.")

Investigation #1 YES ☐ NO ☒

Investigation #2 YES ☐ NO ☒

If you have answered "yes" for one or more investigations, identify each such investigation and the NDA in which each was relied upon:

b) For each investigation identified as "essential to the approval", does the investigation duplicate the results of another investigation that was relied on by the agency to support the effectiveness of a previously approved drug product?

Investigation #1 YES ☐ NO ☒

Investigation #2 YES ☐ NO ☒

If you have answered "yes" for one or more investigation, identify the NDA in which a similar investigation was relied on:

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

FTC-203 - "Open-label, non-randomized trial to evaluate the safety, PK, and anti-HIV activity of FTC (given once daily) in combination with other antiretroviral (ART) agents"
FTC-202 (PACTG-1021) - "Open-label, non-randomized trial to evaluate the safety/tolerability anti-HIV activity and PK of FTC when combined with didanosine (ddI) and efavirenz (EFV) in a fully QD regimen"

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1		!
		!
IND # 53,971	YES ☒	! NO ☐
		! Explain:

Investigation #2		!
		!
IND # 53,971	YES ☒	! NO ☐
		! Explain:

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1	!
	!
YES ☐	! NO ☒
Explain:	! Explain:

Investigation #2	!
	!
YES ☐	! NO ☒
Explain:	! Explain:

(c) Notwithstanding an answer of "yes" to (a) or (b), are there other reasons to believe that the applicant should not be credited with having "conducted or sponsored" the study? (Purchased studies may not be used as the basis for exclusivity. However, if all rights to the drug are purchased (not just studies on the drug), the applicant may be considered to have sponsored or conducted the studies sponsored or conducted by its predecessor in interest.)

YES ☐ NO ☒

If yes, explain:

==========

Name of person completing form: Marsha S. Holloman, BS Pharm, JD
Title: Regulatory Health Project Manager
Date: September 27, 2005

Name of Office/Division Director signing form: Debra B. Birnkrant, JD
Title: Division Director

Form OGD-011347; Revised 05/10/2004; formatted 2/15/05

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/s/

Marsha Holloman
10/19/2005 04:27:35 PM

Debarment Certification

Gilead Sciences, Inc. hereby certifies that Gilead and its contract operations, laboratories or individuals involved in the development or submission of records or data regarding emtricitabine did not use and will not use in any capacity the services of any person debarred under subsections (a) or (b) [section 306(a) or (b)] of the Federal Food, Drug, and Cosmetic Act or the Generic Drug Enforcement Act of 1992 (21 U.S.C. 335a(k)(l)) in connection with this application.

Martine Kraus

Martine Kraus, Ph.D.
Director, Regulatory Affairs

March 15, 2005

Date

PEDIATRIC PAGE

(Complete for all filed original applications and efficacy supplements)

NDA/BLA # : 21-896 Supplement Type (e.g. SE5): _____ Supplement Number:

Stamp Date: March 30, 2005 Action Date: September 30, 2005

HFD 530 Trade and generic names/dosage form: EMTRIVA® (emtricitabine) Oral Solution

Applicant: Gilead Sciences, Inc Therapeutic Class: Antiretroval

Indication(s) previously approved: None

Each approved indication must have pediatric studies: Completed, Deferred, and/or Waived.

Number of indications for this application(s): 1

Indication #1: Treatment of HIV-1 infection, in combination with other antiretroviral agents,

Is there a full waiver for this indication (check one)?

- ☐ Yes: Please proceed to Section A.
- ✔ No: Please check all that apply: ____Partial Waiver ✔Deferred ____Completed
  NOTE: More than one may apply
  Please proceed to Section B, Section C, and/or Section D and complete as necessary.

Section A: Fully Waived Studies

Reason(s) for full waiver:

- ☐ Products in this class for this indication have been studied/labeled for pediatric population
- ☐ Disease/condition does not exist in children
- ☐ Too few children with disease to study
- ☐ There are safety concerns
- ☐ Other:_____

If studies are fully waived, then pediatric information is complete for this indication. If there is another indication, please see Attachment A. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section B: Partially Waived Studies

Age/weight range being partially waived:

Min_____	kg_____	mo._____	yr._____	Tanner Stage_____
Max_____	kg_____	mo._____	yr._____	Tanner Stage_____

Reason(s) for partial waiver:

- ☐ Products in this class for this indication have been studied/labeled for pediatric population
- ☐ Disease/condition does not exist in children
- ☐ Too few children with disease to study
- ☐ There are safety concerns
- ☐ Adult studies ready for approval
- ☐ Formulation needed
- ☐ Other:_____

If studies are deferred, proceed to Section C. If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section C: Deferred Studies

Age/weight range being deferred:

Min _____ **kg**_____ **mo.**_____ **yr.** 0 (birth) **Tanner Stage**_____
Max_____ **kg**_____ **mo.**_____ **yr.** 3 months **Tanner Stage**_____

Reason(s) for deferral:

- ☐ **Products in this class for this indication have been studied/labeled for pediatric population**
- ☐ **Disease/condition does not exist in children**
- ☐ **Too few children with disease to study**
- ☐ **There are safety concerns**
- ☐ **Adult studies ready for approval**
- ☐ **Formulation needed**

Other: Pediatric studies are ongoing. Waiting for the data in younger infants.

Date studies are due (mm/dd/yy): 03/30/2006, as stated in the amended Written Request for IND 51-971 emtricitabine dated December 3, 2004

If studies are completed, proceed to Section D. Otherwise, this Pediatric Page is complete and should be entered into DFS.

Section D: Completed Studies

Age/weight range of completed studies:

Min _____ **kg**_____ **mo.**_____ **yr.**_____ **Tanner Stage**_____
Max_____ **kg**_____ **mo.**_____ **yr.**_____ **Tanner Stage**_____

Comments:

If there are additional indications, please proceed to Attachment A. Otherwise, this Pediatric Page is complete and should be entered into DFS.

This page was completed by:

{See appended electronic signature page}

Marsha S. Holloman, BS Pharm, JD
Regulatory Health Project Manager

cc: NDA 21-896
HFD-960/ Grace Carmouze

FOR QUESTIONS ON COMPLETING THIS FORM CONTACT THE DIVISION OF PEDIATRIC DRUG DEVELOPMENT, HFD-960, 301-594-7337.

(revised 12-22-03)

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/s/

Marsha Holloman
10/14/2005 04:20:30 PM

NDA/EFFICACY SUPPLEMENT ACTION PACKAGE CHECKLIST

Application Information			
NDA 21-896	Efficacy Supplement Type SE-	Supplement Number	
Drug: EMTRIVA® (emtricitabine) Oral Solution		Applicant: Gilead Sciences, Inc	
RHPM: Marsha S. Holloman		HFD-530	Phone # 301-796-0731

Application Type: (✔) 505(b)(1) ( ) 505(b)(2) (This can be determined by consulting page 1 of the NDA Regulatory Filing Review for this application or Appendix A to this Action Package Checklist.) **If this is a 505(b)(2) application, please review and confirm the information previously provided in Appendix B to the NDA Regulatory Filing Review. Please update any information (including patent certification information) that is no longer correct.** ( ) Confirmed and/or corrected	Listed drug(s) referred to in 505(b)(2) application (NDA #(s), Drug name(s)):

❖ Application Classifications:	
• Review priority	() Standard (✔) Priority
• Chem class (NDAs only)	3
• Other (e.g., orphan, OTC)	N/A
❖ User Fee Goal Dates	September 30, 2005
❖ Special programs (indicate all that apply)	(✔) None Subpart H ( ) 21 CFR 314.510 (accelerated approval) ( ) 21 CFR 314.520 (restricted distribution) ( ) Fast Track ( ) Rolling Review ( ) CMA Pilot 1 ( ) CMA Pilot 2
❖ User Fee Information	
• User Fee	(✔) Paid UF ID number
• User Fee waiver	( ) Small business ( ) Public health ( ) Barrier-to-Innovation ( ) Other (specify)
• User Fee exception	( ) Orphan designation ( ) No-fee 505(b)(2) (see NDA Regulatory Filing Review for instructions) ( ) Other (specify)
❖ Application Integrity Policy (AIP)	

• Applicant is on the AIP	( ) Yes (✔) No
• This application is on the AIP	( ) Yes (✔) No
• Exception for review (Center Director's memo)	N/A
• OC clearance for approval	N/A
❖ Debarment certification: verified that qualifying language (e.g., willingly, knowingly) was not used in certification & certifications from foreign applicants are cosigned by US agent.	(✔) Verified
❖ Patent	
• Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought.	(✔) Verified
• Patent certification [505(b)(2) applications]: Verify that a certification was submitted for each patent for the listed drug(s) in the Orange Book and identify the type of certification submitted for each patent.	21 CFR 314.50(i)(1)(*i*)(A) (✔) Verified 21 CFR 314.50(i)(1) ( ) (ii) ( ) (iii)
• [505(b)(2) applications] If the application includes a paragraph III certification, it cannot be approved until the date that the patent to which the certification pertains expires (but may be tentatively approved if it is otherwise ready for approval).	
• [505(b)(2) applications] For each paragraph IV certification, verify that the applicant notified the NDA holder and patent owner(s) of its certification that the patent(s) is invalid, unenforceable, or will not be infringed (review documentation of notification by applicant and documentation of receipt of notice by patent owner and NDA holder). *(If the application does not include any paragraph IV certifications, mark "N/A" and skip to the next box below (Exclusivity)).*	( ) N/A (no paragraph IV certification) ( ) Verified
• [505(b)(2) applications] For each paragraph IV certification, based on the questions below, determine whether a 30-month stay of approval is in effect due to patent infringement litigation. Answer the following questions for each paragraph IV certification: (1) Have 45 days passed since the patent owner's receipt of the applicant's notice of certification? (Note: The date that the patent owner received the applicant's notice of certification can be determined by checking the application. The applicant is required to amend its 505(b)(2) application to include documentation of this date (e.g., copy of return receipt or letter from recipient acknowledging its receipt of the notice) (see 21 CFR 314.52(e))). *If "**Yes**," skip to question (4) below. If "**No**," continue with question (2).* (2) Has the patent owner (or NDA holder, if it is an exclusive patent licensee) submitted a written waiver of its right to file a legal action for patent infringement after receiving the applicant's notice of certification, as provided for by 21 CFR 314.107(f)(3)? *If "**Yes**," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next box below (Exclusivity).* *If "**No**," continue with question (3).* (3) Has the patent owner, its representative, or the exclusive patent licensee	( ) Yes ( ) No ( ) Yes ( ) No ( ) Yes ( ) No

filed a lawsuit for patent infringement against the applicant? (Note: This can be determined by confirming whether the Division has received a written notice from the applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2))). *If "**No**," the patent owner (or NDA holder, if it is an exclusive patent licensee) has until the expiration of the 45-day period described in question (1) to waive its right to bring a patent infringement action or to bring such an action. After the 45-day period expires, continue with question (4) below.*	
(4) Did the patent owner (or NDA holder, if it is an exclusive patent licensee) submit a written waiver of its right to file a legal action for patent infringement within the 45-day period described in question (1), as provided for by 21 CFR 314.107(f)(3)? *If "**Yes**," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next box below (Exclusivity).* *If "**No**," continue with question (5).*	( ) Yes ( ) No
(5) Did the patent owner, its representative, or the exclusive patent licensee bring suit against the applicant for patent infringement within 45 days of the patent owner's receipt of the applicant's notice of certification? (Note: This can be determined by confirming whether the Division has received a written notice from the applicant (or the patent owner or its representative) stating that a legal action was filed within 45 days of receipt of its notice of certification. The applicant is required to notify the Division in writing whenever an action has been filed within this 45-day period (see 21 CFR 314.107(f)(2)). If no written notice appears in the NDA file, confirm with the applicant whether a lawsuit was commenced within the 45-day period). *If "**No**," there is no stay of approval based on this certification. Analyze the next paragraph IV certification in the application, if any. If there are no other paragraph IV certifications, skip to the next box below (Exclusivity).* *If "**Yes**," a stay of approval may be in effect. To determine if a 30-month stay is in effect, consult with the Director, Division of Regulatory Policy II, Office of Regulatory Policy (HFD-007) and attach a summary of the response.*	( ) Yes ( ) No
❖ Exclusivity (approvals only)	
• Exclusivity summary • Is there remaining 3-year exclusivity that would bar effective approval of a 505(b)(2) application? (Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)	(✔) Yes (✔) No
• Is there existing orphan drug exclusivity protection for the "same drug" for the proposed indication(s)? *Refer to 21 CFR 316.3(b)(13) for the definition of "same drug" for an orphan drug (i.e., active moiety). This definition is NOT the same as that used for NDA chemical classification.*	( ) Yes, Application #_____ (✔) No
❖ Administrative Reviews (Project Manager, ADRA) *(indicate date of each review)*	N/A

General Information	
Actions	
• Proposed action	(✔) AP ( ) TA ( ) AE ( ) NA
• Previous actions (specify type and date for each action taken)	N/A
• Status of advertising (approvals only)	(✔) Materials requested in AP letter ( ) Reviewed for Subpart H
❖ Public communications	
• Press Office notified of action (approval only)	( ) Yes (✔) Not applicable
• Indicate what types (if any) of information dissemination are anticipated	(✔) None ( ) Press Release ( ) Talk Paper ( ) Dear Health Care Professional Letter
❖ Labeling (package insert, patient package insert (if applicable), MedGuide (if applicable))	
• Division's proposed labeling (only if generated after latest applicant submission of labeling)	N/A
• Most recent applicant-proposed labeling	✔ 09/26/2005
• Original applicant-proposed labeling	✔ 03/05/2005
• Labeling reviews (including DDMAC, DMETS, DSRCS) and minutes of labeling meetings *(indicate dates of reviews and meetings)*	N/A
• Other relevant labeling (e.g., most recent 3 in class, class labeling)	N/A
❖ Labels (immediate container & carton labels)	
• Division proposed (only if generated after latest applicant submission)	N/A
• Applicant proposed	✔ 09/26/2005
• Reviews	✔ See Chemistry Review
❖ Post-marketing commitments	
• Agency request for post-marketing commitments	✔ 09/22/2005
• Documentation of discussions and/or agreements relating to post-marketing commitments	✔ 09/27/2005
❖ Outgoing correspondence (i.e., letters, E-mails, faxes)	✔
❖ Memoranda and Telecons	✔
❖ Minutes of Meetings	
• EOP2 meeting (indicate date)	✔
• Pre-NDA meeting (indicate date)	N/A
• Pre-Approval Safety Conference (indicate date; approvals only)	N/A
• Other	✔
❖ Advisory Committee Meeting	
• Date of Meeting	N/A
• 48-hour alert	N/A
❖ Federal Register Notices, DESI documents, NAS/NRC reports (if applicable)	N/A

Summary Application Review	
Summary Reviews (e.g., Office Director, Division Director, Medical Team Leader) *(indicate date for each review)*	✔ MOTL Memo 09/26/2005
Clinical Information	
❖ Clinical review(s) *(indicate date for each review)*	✔ 09/26/2005
❖ Microbiology (efficacy) review(s) *(indicate date for each review)*	✔ 09/01/2005
❖ Safety Update review(s) *(indicate date or location if incorporated in another review)*	N/A
❖ Risk Management Plan review(s) *(indicate date/location if incorporated in another rev)*	N/A
❖ Pediatric Page(separate page for each indication addressing status of all age groups)	✔ 09/27/2005 (10/14/2005)
❖ Demographic Worksheet *(NME approvals only)*	N/A
❖ Statistical review(s) *(indicate date for each review)*	✔ 09/28/2005
❖ Biopharmaceutical review(s) *(indicate date for each review)*	✔ 09/27/2005
❖ Controlled Substance Staff review(s) and recommendation for scheduling *(indicate date for each review)*	N/A
❖ Clinical Inspection Review Summary (DSI)	
• Clinical studies	✔ 08/24/2005
• Bioequivalence studies	N/A
CMC Information	
❖ CMC review(s) *(indicate date for each review)*	✔ 09/23/2005
❖ Environmental Assessment	
• Categorical Exclusion *(indicate review date)*	✔
• Review & FONSI *(indicate date of review)*	N/A
• Review & Environmental Impact Statement *(indicate date of each review)*	✔ See CMC Review
❖ Microbiology (validation of sterilization & product sterility) review(s) *(indicate date for each review)*	N/A
❖ Facilities inspection (provide EER report) **See CMC Review**	Date completed: (✔) Acceptable ( ) Withhold recommendation
❖ Methods validation	(✔) Completed ( ) Requested ( ) Not yet requested
Nonclinical Pharm/Tox Information	
❖ Pharm/tox review(s), including referenced IND reviews *(indicate date for each review)*	✔ 05/11/2005
❖ Nonclinical inspection review summary	N/A
❖ Statistical review(s) of carcinogenicity studies *(indicate date for each review)*	N/A
❖ CAC/ECAC report	N/A

Appendix A to NDA/Efficacy Supplement Action Package Checklist

An application is likely to be a 505(b)(2) application if:

(1) it relies on literature to meet any of the approval requirements (unless the applicant has a written right of reference to the underlying data)
(2) it relies on the Agency's previous approval of another sponsor's drug product (which may be evidenced by reference to publicly available FDA reviews, or labeling of another drug sponsor's drug product) to meet any of the approval requirements (unless the application includes a written right of reference to data in the other sponsor's NDA)
(3) it relies on what is "generally known" or "scientifically accepted" about a class of products to support the safety or effectiveness of the particular drug for which the applicant is seeking approval. (Note, however, that this does not mean *any* reference to general information or knowledge (e.g., about disease etiology, support for particular endpoints, methods of analysis) causes the application to be a 505(b)(2) application.)
(4) it seeks approval for a change from a product described in an OTC monograph and relies on the monograph to establish the safety or effectiveness of one or more aspects of the drug product for which approval is sought (see 21 CFR 330.11).

Products that may be likely to be described in a 505(b)(2) application include combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations), OTC monograph deviations, new dosage forms, new indications, and new salts.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, please consult with the Director, Division of Regulatory Policy II, Office of Regulatory Policy (HFD-007).

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/s/

Marsha Holloman
10/14/2005 05:10:37 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

Date: **August 18, 2005**

NDA: **21-896**

Drug: **Emtricitabine Oral Solution**

To: **Pamela L. Danagher**

Sponsor: **Gilead Sciences**

From: **Kenny Shade, JD, BSN**

Through: **Russell Fleischer, PA-C, M.P.H.**

Concurrence: **Katherine Laessig, M.D.**

Subject: **Clinical Comments**

The following comments are being conveyed to you on behalf of the review team. Please refer to your NDA 21-896 for Emtricitabine Oral Solution.

1. We note that pediatric patients experienced substantially more vomiting and gastroenteritis compared to adults. Please comment on these findings and also provide information on the need for re-dosing due to gastrointestinal adverse events.

2. Please provide a narrative for patient 483-575 in study FTC-203, that describes the severity of hyperpigmentation.

3. Please provide a listing of all patients with new CDC class C or greater events in study FTC-202.

We are providing this above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me at 301-827-2335 if you have any questions regarding the contents of this transmission.

Kenny Shade, JD, BSN
Regulatory Project Manager
Division of Antiviral Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV
Division of Antiviral Drug Products

FACSIMILE TRANSMITTAL SHEET

DATE: August 18, 2005

To: Pamela L. Danagher, Associate Director, Regulatory Affairs	**From: Kenny Shade, JD, BSN** Division of Antiviral Drug Products
Company: Gilead Sciences	**Title: Regulatory Project Manager**
Fax number: 650-522-5489	**Fax number: 301-827-2471**
Phone number: 650-522-6395	**Phone number: 301-827-2335**

Subject: Clinical Comments

Total number of pages including cover: 2

Comments:

Document to be mailed: • YES ☑ NO

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/s/

Kenny Shade
8/18/2005 02:15:08 PM
CSO

Kathrine Laessig
8/22/2005 03:02:13 PM
MEDICAL OFFICER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

MEMORANDUM OF FACSIMILE CORRESPONDENCE

NDA: 21-896

Drug: EMTRIVA® (emtricitabine) Oral Solution

Date: August 1, 2005

To: Pamela Danagher, MSc, Associate Director, Regulatory Affairs

Sponsor: Gilead Sciences, Inc.

From: Jeff D. O'Neill, ACRN, Regulatory Health Project Manager, DAVDP

Through: Jennifer DiGiacinto, PharmD, Clinical Pharmacologist, DAVDP

Concurrence: Katherine Laessig, MD, Medical Officer Team Leader, DAVDP
Russ Fleischer, PA-C, MPH, Senior Clinical Analyst, DAVDP
Kellie S. Reynolds, PharmD, Clinical pharmacology Team Leader, DAVDP

Subject: Clinical pharmacology comments regarding your NDA 21-896 submission dated March 29, 2005 submission.

The following clinical pharmacology comments are on behalf of Jennifer DiGiacinto, PharmD:

1. EMTRIVA® Oral Solution may be administered to patients with renal impairment. NDA 21-896 does not propose any dosing guidelines in the product label for this new oral solution formulation in this patient population. Below is proposed dosing for the EMTRIVA® Oral Solution formulation for patients with renal impairment. Please review and agree or provide a counter proposal for inclusion in product label.

Proposed Renal Impairment Dosing with the FTC Oral Solution

Formulation	> 50 mL/min	30-49mL/min	29-15 mL/min	< 15-mL/min or on hemodialysis
Capsule	200-mg QD	200-mg Q48H	200-mg Q72H	200-mg Q96H
Oral Solution	240-mg QD	120-mg QD	80-mg QD	60-mg QD

2. Please submit the Lot #, Manufacturer's Lot #, and Expiration Dates for the EMTRIVA® Oral Solution and EMTRIVA® Capsule administered in Study FTC-202 (PACTG1021).

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV
Division of Antiviral Drug Products

FACSIMILE TRANSMITTAL SHEET

DATE: August 1, 2005

To: Pamela Danagher	From: Jeff D. O'Neill
Company: Gilead Sciences, Inc.	Title: Regulatory Health Project Manager, HFD-530
Fax number: 650-522-5489	Fax number: 301-827-2510
Phone number: 650-522-6395	Phone number: 301-827-2362

Subject: Clinical pharmacology comments regarding NDA 21-896 for Emtriva Oral Solution.

Total no. of pages including cover: 3

Comments:

Document to be mailed: ☐ YES ☑ NO

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/s/

Jeff ONeill
8/1/05 02:26:09 PM
CSO

Clin Pharm fax for NDA 21-896. Hard copy sign-off 8/1/05

Kathrine Laessig
8/1/05 02:43:49 PM
MEDICAL OFFICER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

MEMORANDUM OF FACSIMILE CORRESPONDENCE

NDA:	**21-896**
Drug:	**EMTRIVA® (emtricitabine) Oral Solution**
Date:	**July 8, 2005**
To:	**Pamela Danagher, MSc, Associate Director, Regulatory Affairs**
Sponsor:	**Gilead Sciences, Inc.**
From:	**Jeff D. O'Neill, ACRN, Regulatory Health Project Manager, DAVDP**
Through:	**Susan Zhou, PhD, Statistical Reviewer, DAVDP**
Concurrence:	**Katherine Laessig, MD, Medical Officer Team Leader, DAVDP** **Greg Soon, PhD, Statistical Team Leader, DAVDP**
Subject:	**Statistical comments regarding NDA 21-896 for Emtriva Oral Solution.**

Please address the following data problems in SAS *XPT* files of Studies FTC211 and FTC203:

1. In SAS file *adkeyvar.xpt* of FTC211, the PATIDs for sixteen subjects are not the same as those in other XPT files such as *demog, ae, dose, endstudy* and *labs*.

2. In SAS files *adkeyvar.xpt* of FTC211 and FTC203, it is unclear how the baseline values for plasma viral load, CD4+ cell count and CD4% were calculated. The variable names are BL_HIV, BL_CD4D, BL_CD4P in Study FTC203, and B_HIV, B_CD4, and B_CD4P in Study FTC211.

3. Multiple laboratory measurements of plasma HIV-1 RNA per visit date were observed in SAS files *labs.xpt*. It is unclear how the repeated viral load data were coded and what was the definition for the time window in generating these key parameters in *adkeyvar.xpt*.

4. Some of the ART experienced subjects in FTC203 had no HIV RNA detected (<400 copies/mL or <50 copies/mL) prior to and at baseline. In Table 3 (Page 25, Section 2.7.3 Summary of Clinical Efficacy), please provide the number and percentage of subjects with undetectable HIV RNA at baseline.

Please submit revised data set file *adkeyvar.xpt* for Study FTC211, and efficacy datasets for Study FTC202. Please provide a detailed description of the definition of time window, approach of dealing with repeated HIV RNA measurements, and SAS programs for the computations of key variables in the files *adkeyvar.xpt*. Please send your response by July 25, 2005 in order to facilitate the continuation of the review process.

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV
Division of Antiviral Drug Products

FACSIMILE TRANSMITTAL SHEET

DATE: July 8, 2005

To: Pamela Danagher	From: Jeff D. O'Neill
Company: Gilead Sciences, Inc.	Title: Regulatory Health Project Manager, HFD-530
Fax number: 650-522-5489	Fax number: 301-827-2510
Phone number: 650-522-6395	Phone number: 301-827-2362
Subject: NDA 21-896 for Emtriva oral solution.	
Total no. of pages including cover: 3	
Comments:	

Document to be mailed: ☐ YES ☑ NO

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/s/

Jeff ONeill
7/8/05 11:12:29 AM
CSO

Stats Fax for NDA 21-896 Emtriva. Hard copy sign-off 7/8/05

Kathrine Laessig
7/12/05 11:44:21 AM
MEDICAL OFFICER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

MEMORANDUM OF FACSIMILE CORRESPONDENCE

NDA:	**21-896**
Drug:	**EMTRIVA® (emtricitabine) Oral Solution**
Date:	**June 16, 2005**
To:	**Pamela Danagher, MSc, Associate Director, Regulatory Affairs**
Sponsor:	**Gilead Sciences, Inc.**
From:	**Jeff D. O'Neill, ACRN, Regulatory Health Project Manager, DAVDP**
Through:	**Russ Fleischer, PA-C, MPH, Medical Reviewer, DAVDP**
Concurrence:	**Katherine Laessig, MD, Medical Officer Team Leader, DAVDP**
Subject:	**Clinical comments regarding NDA 21-896 for Emtriva Oral Solution.**

The following clinical comments are on behalf of Russ Fleischer, PA-C, MPH:

FTC-203:

- Provide a more detailed breakdown of patients classified with an ethnic origin of "other."
- The median change in CD4 cell counts among treatment experienced patients was -59.5 (-945 to +712). Please explain this finding.

FTC-202:

- Please describe the follow-up for patient 400873. Specifically did the patient's GGT return to normal levels and when, and was he on or off therapy at the time?
- Please recalculate, using the TLOVR algorithm, the data in Tables 5-10 and 5-11 using the ITT population of 37 patients.

FTC-211:

- Please identify the age and gender of patient #5108.

Overall NDA:

- Please provide the required analysis of safety and efficacy by race.
- Please provide the required analysis of safety and efficacy by gender.
- Please provide an assessment of changes in growth and development.
- Provide a regulatory history of milestones in pediatric development.
- The WHO recommended limit of propylene glycol is [redacted] day. At the proposed 6 mg/kg/day dose of emtricitabine oral solution, patients would receive [redacted] of propylene glycol. Please discuss the clinical relevance of this amount of propylene glycol in pediatric patients, especially children <4 years of age. Further, please discuss with respect to other medications including propylene glycol that might be co-administered with emtricitabine oral solution to pediatric patients, e.g., ritonavir. Relevant references can be found in Martindale's. Finally, please provide draft precautionary labeling language.

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV
Division of Antiviral Drug Products

FACSIMILE TRANSMITTAL SHEET

DATE: June 16, 2005

To: Pamela Danagher	From: Jeff D. O'Neill
Company: Gilead Sciences, Inc.	Title: Regulatory Health Project Manager, HFD-530
Fax number: 650-522-5489	Fax number: 301-827-2510
Phone number: 650-522-6395	Phone number: 301-827-2362

Subject: NDA 21-896 for Emtriva oral solution.

Total no. of pages including cover: 3

Comments:

Document to be mailed: • YES ☑ NO

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/s/

Jeff ONeill
6/16/05 02:40:39 PM
CSO

Emtriva NDA 21-896 clinical Fax. Hard copy sign-off 6/16/05

Kathrine Laessig
6/16/05 04:14:29 PM
MEDICAL OFFICER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

FILING COMMUNICATION

NDA 21-896

Gilead Sciences, Inc.
Attention: Pamela Danagher, M.Sc.
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Danagher:

Please refer to your March 29, 2005 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Emtriva® (emtricitabine) Oral Solution 10 mg/ml.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, this application will be filed under section 505(b) of the Act on June 3, 2005 in accordance with 21 CFR 314.101(a).

At this time, we have not identified any potential filing review issues. Our filing review is only a preliminary evaluation of the application and is not indicative of deficiencies that may be identified during our review.

If you have any questions, call Jeff D. O'Neill, Regulatory Health Project Manager, at (301) 827-2362.

Sincerely,

{See appended electronic signature page}
Debra Birnkrant, MD
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

Debra Birnkrant
5/18/05 10:08:42 AM
NDA 21-896

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

MEMORANDUM OF FACSIMILE CORRESPONDENCE

NDA: 21-896

Drug: EMTRIVA® (emtricitabine) Oral Solution

Date: April 27, 2005

To: Pamela Danagher, MSc, Associate Director, Regulatory Affairs

Sponsor: Gilead Sciences, Inc.

From: Jeff D. O'Neill, ACRN, Regulatory Health Project Manager, DAVDP

Through: George Lunn, Ph.D., Chemistry Reviewer, DAVDP

Concurrence: Stephen P. Miller, Chemistry Team Leader, DAVDP

Subject: Chemistry comment regarding your March 29, 2005 submission.

The following chemistry comment is on behalf of George Lunn, Ph.D:

- Please provide a complete quantitative list of all the components of Cotton Candy Flavor F-9967, with FEMA references or equivalent, or a Letter of Authorization to refer to a Drug Master File (DMF) that contains this information.

- For HPLC Method TM-045 you state that the detector response for 5-fluorocytosine, FTU, and FTC-sulfoxides is linear (3.2.P.5.3, p. 52). Please supply the correlation coefficients for these linearity plots.

- Please confirm that FTC-menthyl ester does not interfere with HPLC method TM-045.

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV
Division of Antiviral Drug Products

FACSIMILE TRANSMITTAL SHEET

DATE: April 27, 2005

To: Pamela Danagher	From: Jeff D. O'Neill
Company: Gilead Sciences, Inc.	Title: Regulatory Health Project Manager, HFD-530
Fax number: 650-522-5489	Fax number: 301-827-2510
Phone number: 650-522-6395	Phone number: 301-827-2362

Subject: NDA 21-896 for Emtriva oral solution.

Total no. of pages including cover: 2

Comments:

Document to be mailed: ☐ YES ☑ NO

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/s/

Jeff ONeill
4/27/05 09:04:38 AM
CSO

21896 Emtriva Oral Solution, chemistry fax. Hard copy sing-off
4/27/05

Stephen Paul Miller
4/27/05 10:51:34 AM
CHEMIST

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

MEMORANDUM OF FACSIMILE CORRESPONDENCE

NDA: 21-752

Drug: EMTRIVA® (emtricitabine) Oral Solution

Date: April 14, 2005

To: Pamela Danagher, MSc, Associate Director, Regulatory Affairs

Sponsor: Gilead Sciences, Inc.

From: Jeff D. O'Neill, ACRN, Regulatory Health Project Manager, DAVDP

Through: Russ Fleischer, PA-C, MPH, Senior Clinical Analyst, DAVDP

Concurrence: Katherine Laessig, MD, Medical Officer Team Leader, DAVDP

Subject: Clinical comment regarding your March 29, 2005 submission.

The following clinical comment is on behalf of Russ Fleischer, PA-C, MPH:

- For each patient classified as "experienced" in the NDA, please provide a listing of all previous regimens with start and stop dates and reason(s) for stopping. For the baseline regimen, provide the drugs in the regimen, baseline HIV RNA, and baseline CD4 cell counts.

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV
Division of Antiviral Drug Products

FACSIMILE TRANSMITTAL SHEET

DATE: April 14, 2005

To: Pamela Danagher	From: Jeff D. O'Neill
Company: Gilead Sciences, Inc.	Title: Regulatory Health Project Manager, HFD-530
Fax number: 650-522-5489	Fax number: 301-827-2510
Phone number: 650-522-6395	Phone number: 301-827-2362

Subject: Clinical comment regarding NDA 21-896 for Emtriva oral solution.

Total no. of pages including cover: 2

Comments:

Document to be mailed: ☐ YES ☑ NO

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/s/

Jeff ONeill
4/14/05 01:52:38 PM
CSO

21-896 Clinical comments for 3.29.05 submission. Hard copy sign-off 4/14/05

Kathrine Laessig
4/14/05 03:25:16 PM
MEDICAL OFFICER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-896

Gilead Sciences, Inc.
Attention: Pamela Danagher, M.Sc.
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Danagher:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Emtriva® (emtricitabine) Oral Solution 10 mg/ml

Date of Application: March 29, 2005

Date of Receipt: March 30, 2005

Our Reference Number: NDA 21-896

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on May 30, 2005 in accordance with 21 CFR 314.101(a).

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have submitted pediatric studies with this application. Once the review of this application is complete, we will notify you whether you have fulfilled the pediatric study requirement for this application. In addition, we acknowledge that additional studies will be submitted at a later time.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Send all electronic or mixed electronic and paper submissions to the Central Document Room at the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 20705-1266

If your submission only contains paper, send it to the following address:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Antiviral Drug Products, HFD-530
Attention: Document Room Control Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Antiviral Drug Products, HFD-530
Attention: Document Room, N115
9201 Corporate Boulevard, HFD-530
Rockville, Maryland 20805

If you have any questions, call Jeff D. O'Neill, Regulatory Health Project Manager, at (301) 827-2362.

Sincerely,

{See appended electronic signature page}
Virginia Behr
Chief, Project Management Staff
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

Virginia Behr
4/13/05 01:20:14 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Division of Antiviral Drug Products
Food and Drug Administration
Rockville MD 20857

MEMORANDUM OF FACSIMILE CORRESPONDENCE

NDA: 21-752

Drug: EMTRIVA® (emtricitabine) Oral Solution

Date: April 12, 2005

To: Pamela Danagher, M.Sc., Associate Director, Regulatory Affairs

Sponsor: Gilead Sciences, Inc.

From: Jeff D. O'Neill, ACRN, Regulatory Health Project Manager, DAVDP

Through: George Lunn, Ph.D., Chemistry Reviewer, DAVDP

Concurrence: Stephen P. Miller, Ph.D., Chemistry Team Leader, DAVDP

Subject: Chemistry comment regarding your March 29, 2005 submission.

The following chemistry comment is on behalf of George Lunn, Ph.D:

Please refer to your recently submitted NDA 21-896 for Emtriva (emtricitabine) oral solution and in particular the list of establishments supplied as an addendum to Form 356H. Please specify which establishments are to be used for release testing and which for stability testing.

We are providing the above information via telephone facsimile for your convenience. **THIS MATERIAL SHOULD BE VIEWED AS UNOFFICIAL CORRESPONDENCE.** Please feel free to contact me if you have any questions regarding the contents of this transmission.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation IV
Division of Antiviral Drug Products

FACSIMILE TRANSMITTAL SHEET

DATE: April 12, 2005

To: Pamela Danagher	From: Jeff D. O'Neill
Company: Gilead Sciences, Inc.	Title: Regulatory Health Project Manager, HFD-530
Fax number: 650-522-5489	Fax number: 301-827-2510
Phone number: 650-522-6395	Phone number: 301-827-2362

Subject: Chemistry comment regarding NDA 21-896 for Emtriva oral solution.

Total no. of pages including cover: 2

Comments:

Document to be mailed: ☐ YES ☑ NO

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/s/

Jeff ONeill
4/12/05 02:56:07 PM
CSO

Chemistry comments regarding NDA 21896. Hard copy sign-off 04/12/05

Stephen Paul Miller
4/12/05 05:17:37 PM
CHEMIST

GILEAD
Advancing Therapeutics.
Improving Lives.

15 March 2005

U.S. Food and Drug Administration (360909)
Attn. Beverly J. Friedman
Mellon Client Service Center, Room 670
500 Ross Street
Pittsburgh, PA 15262-0001

Subject: **NDA 21-896: Emtriva (emtricitabine) Oral Solution**
User Fee Payment – Original NDA, ID #3006011

Dear Ms. Friedman:

Gilead Sciences (Gilead) hereby submits the user fee payment in the amount of $672,000.00 for the NDA 21-896. The user fee ID number assigned to this submission is 3006011.

Please contact me at 650-522-6395 or via facsimile at 650-522-5489 if you have any questions or need additional information. You may also contact, Dr. Martine Kraus, Director, Regulatory Affairs, at 650-522-5722. We share the same facsimile number.

Sincerely,

Pamela L. Danagher, M.Sc.
Associate Director, Regulatory Affairs

Enclosures: 1 original with check

Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA
phone 650 574 3000 *facsimile* 650 578 9264

www.gilead.com

Form Approved: OMB No. 0910 - 0297 Expiration Date: December 31, 2006 See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	PRESCRIPTION DRUG USER FEE COVERSHEET

A completed form must be signed and accompany each new drug or biologic product application and each new supplement. See exceptions on the reverse side. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment instructions and fee rates can be found on CDER's website: http://www.fda.gov/cder/pdufa/default.htm

1. APPLICANT'S NAME AND ADDRESS

GILEAD SCIENCES
Pamela Danagher, M.Sc.
Gilead Sciences, Inc. 333 Lakeside Drive
Foster City CA 94404
US

4. BLA SUBMISSION TRACKING NUMBER (STN) / NDA NUMBER

21896

2. TELEPHONE NUMBER
650-522-6395

5. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL?

[X] YES [ ] NO

IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM. IF RESPONSE IS "YES", CHECK THE APPROPRIATE RESPONSE BELOW:

[X] THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION

[ ] THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO:

3. PRODUCT NAME
Emtriva (emtricitabine oral solution)

6. USER FEE I.D. NUMBER
3006011

7. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.

[ ] A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT BEFORE 9/1/92 (Self Explanatory)

[ ] A 505(b)(2) APPLICATION THAT DOES NOT REQUIRE A FEE

[ ] THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(E) of the Federal Food,Drug, and Cosmetic Act

[ ] THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALLY

8. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION? [ ] YES [X] NO

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewinginstructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CBER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER, HFD-94
12420 Parklawn Drive, Room 3046
Rockville, MD 20852

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SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE	TITLE	DATE
Pamela Danagher	Associate Director, Regulatory Affairs	March 15 2005

9. USER FEE PAYMENT AMOUNT FOR THIS APPLICATION
$672,000.00

Form FDA 3397 (12/03)

Close Print Cover sheet