

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22-565

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

**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*

NDA NUMBER

22-565

NAME OF APPLICANT/NDA HOLDER

Wyeth Consumer Healthcare, A Division of
Wyeth

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)

Advil Cold & Sinus PE

ACTIVE INGREDIENT(S)

Ibuprofen
Phenylephrine Hydrochloride

STRENGTH(S)

200mg
10 mg

DOSAGE FORM

CAPLET (oval shaped tablet)

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 submit 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 5,087,454	b. Issue Date of Patent 2/11/1992	c. Expiration Date of Patent 7/30/2010
d. Name of Patent Owner Wyeth	Address (of Patent Owner) Five Giralda Farms	
	City/State Madison, NJ	
	ZIP Code 07940	FAX Number (if available)
	Telephone Number 973-660-6975	E-Mail Address (if available)
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) David Manspeizer Vice President of Intellectual Property	Address (of agent or representative named in 1.e.) Five Giralda Farms	
	City/State Madison, NJ	
	ZIP Code 07940	FAX Number (if available) 973-660-7151
	Telephone Number 973-660-7666	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? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
g. If the patent referenced above has been submitted previously for listing, is the expiration date a new expiration date? <input type="checkbox"/> Yes <input type="checkbox"/> 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 for each method of using the pending drug product for which approval is being sought that is claimed by the patent. For each pending method of use claimed by the patent, 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(s) (as listed in the patent) Does (Do) the patent claim(s) 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 proposed labeling.)

5. No Relevant Patents

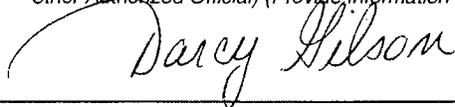
For this pending NDA, amendment, or supplement, there are no relevant patents that claim the drug substance (active ingredient), drug product (formulation or composition) or method(s) of use, for which the applicant is seeking approval and with respect to which a claim of patent infringement could reasonably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

07/24/2009

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

Darcy Gilson

Address

Five Giralda Farms

City/State

Madison, New Jersey

ZIP Code

07940

Telephone Number

973-660-6975

FAX Number (if available)

973-660-7180

E-Mail Address (if available)

gilsond@wyeth.com

The public reporting burden for this collection of information has been estimated to average 20 hours per response, including the time for reviewing instructions, 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
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Ibuprofen 200 mg/Phenylephrine 10 mg
NDA 22-565

Module 1 Administrative Information
1.3.5.2 Patent Certification

1.3.5.2 Patent certification

Pursuant to 21 CFR § 314.50 (i), in the opinion and to the best knowledge of Wyeth Consumer Healthcare, a division of Wyeth, there are no patents that claim the drug or drugs on which investigations that are relied upon in this application were conducted or that claim a use of such drug or drugs.

WYETH CONSUMER HEALTHCARE



Darcy Gilson
Associate Director
Global Regulatory Affairs

07-24-2009

Date

1.3.5.2 Patent certification

Pursuant to 21 CFR § 314.50 (i), in the opinion and to the best knowledge of Wyeth Consumer Healthcare, a division of Wyeth, there are no patents that claim the drug or drugs on which investigations that are relied upon in this application were conducted or that claim a use of such drug or drugs.

WYETH CONSUMER HEALTHCARE

 07-24-2009
Darcy Gilson Date
Associate Director
Global Regulatory Affairs

EXCLUSIVITY SUMMARY

NDA # 22565

SUPPL #

HFD # 560

Trade Name Advil Congestion Relief

Generic Name Ibuprofen 200 mg and Phenylephrine HCl 10 mg

Applicant Name Wyeth Consumer Healthcare

Approval Date, If Known May 27, 2010

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)(2)

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?

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#

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# 21394	Advil PM Caplets
NDA# 19012	Motrin IB
NDA# 19771	Advil Cold & Sinus PSE

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:

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

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: Janice Adams-King
Title: Regulatory Project Manager
Date: May 25, 2010

Name of Office/Division Director signing form: Joel Schiffenbauer, M.D.
Title: Deputy Director, Division of Nonprescription Clinical Evaluation

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

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22565

ORIG-1

WYETH
CONSUMER
HEALTHCARE

Advil Congestion Relief

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

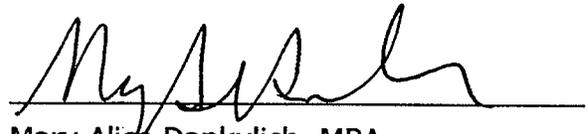
JANICE Adams
06/03/2010

JOEL SCHIFFENBAUER
06/03/2010

1.3.3 Debarment Certification

Wyeth Consumer Healthcare hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of Federal Food, Drug, and Cosmetic Act in connection with this application, Advil® Cold & Sinus PE, NDA 22-565 (Caplets).

WYETH CONSUMER HEALTHCARE

A handwritten signature in black ink, appearing to read 'Mary Alice Dankulich', is written over a horizontal line.

Mary Alice Dankulich, MBA
Vice President, Global R & D
Strategy, Operations, & Compliance

ACTION PACKAGE CHECKLIST

APPLICATION INFORMATION ¹		
NDA # 22565 BLA #	NDA Supplement # BLA STN #	If NDA, Efficacy Supplement Type:
Proprietary Name: Advil Congestion Relief Established/Proper Name: Ibuprofen and Phenylephrine Dosage Form: Caplet (capsule shaped tablet)		Applicant: Wyeth Consumer Healthcare Agent for Applicant (if applicable):
RPM: Janice Adams-King		Division: Nonprescription Clinical Evaluation
<p>NDA: NDA Application Type: <input type="checkbox"/> 505(b)(1) <input checked="" type="checkbox"/> 505(b)(2) Efficacy Supplement: <input type="checkbox"/> 505(b)(1) <input type="checkbox"/> 505(b)(2)</p> <p>(A supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2). Consult page 1 of the 505(b)(2) Assessment or the Appendix to this Action Package Checklist.)</p>		<p>505(b)(2) Original NDAs and 505(b)(2) NDA supplements: Listed drug(s) referred to in 505(b)(2) application (include NDA/ANDA #(s) and drug name(s): Motrin IB/ NDA 19012</p> <p>Provide a brief explanation of how this product is different from the listed drug. Combination product that includes phenylephrine</p> <p><input type="checkbox"/> If no listed drug, check box and explain:</p> <p style="color: red;"><u>Two months prior to each action, review the information in the 505(b)(2) Assessment and submit the draft to CDER OND IO for clearance. Finalize the 505(b)(2) Assessment at the time of the approval action.</u></p> <p><u>On the day of approval, check the Orange Book again for any new patents or pediatric exclusivity.</u></p> <p><input type="checkbox"/> No changes <input type="checkbox"/> Updated Date of check:</p> <p>If pediatric exclusivity has been granted or the pediatric information in the labeling of the listed drug changed, determine whether pediatric information needs to be added to or deleted from the labeling of this drug.</p>
❖ Actions		
<ul style="list-style-type: none"> • Proposed action • User Fee Goal Date is <u>May 28, 2010</u> 		<input checked="" type="checkbox"/> AP <input type="checkbox"/> TA <input type="checkbox"/> CR
<ul style="list-style-type: none"> • Previous actions (<i>specify type and date for each action taken</i>) 		<input type="checkbox"/> None
❖ If accelerated approval, were promotional materials received? Note: For accelerated approval (21 CFR 314.510/601.41), promotional materials to be used within 120 days after approval must have been submitted (for exceptions, see http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm069965.pdf). If not submitted, explain _____		<input type="checkbox"/> Received

¹ The **Application Information** section is (only) a checklist. The **Contents of Action Package** section (beginning on page 5) lists the documents to be included in the Action Package.

❖ Application Characteristics ²	
<p>Review priority: <input checked="" type="checkbox"/> Standard <input type="checkbox"/> Priority Chemical classification (new NDAs only): 4</p> <p> <input type="checkbox"/> Fast Track <input type="checkbox"/> Rx-to-OTC full switch <input type="checkbox"/> Rolling Review <input type="checkbox"/> Rx-to-OTC partial switch <input type="checkbox"/> Orphan drug designation <input checked="" type="checkbox"/> Direct-to-OTC </p> <p> NDAs: Subpart H <input type="checkbox"/> Accelerated approval (21 CFR 314.510) <input type="checkbox"/> Restricted distribution (21 CFR 314.520) Subpart I <input type="checkbox"/> Approval based on animal studies </p> <p> BLAs: Subpart E <input type="checkbox"/> Accelerated approval (21 CFR 601.41) <input type="checkbox"/> Restricted distribution (21 CFR 601.42) Subpart H <input type="checkbox"/> Approval based on animal studies </p> <p> <input type="checkbox"/> Submitted in response to a PMR <input type="checkbox"/> Submitted in response to a PMC <input type="checkbox"/> Submitted in response to a Pediatric Written Request </p> <p>Comments:</p>	
❖ BLAs only: <i>RMS-BLA Product Information Sheet for TBP</i> has been completed and forwarded to OBPS/DRM (<i>approvals only</i>)	<input type="checkbox"/> Yes, date
❖ BLAs only: Is the product subject to official FDA lot release per 21 CFR 610.2 (<i>approvals only</i>)	<input type="checkbox"/> Yes <input type="checkbox"/> No
❖ Public communications (<i>approvals only</i>)	
• Office of Executive Programs (OEP) liaison has been notified of action	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
• Press Office notified of action (by OEP)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
• Indicate what types (if any) of information dissemination are anticipated	<input checked="" type="checkbox"/> None <input type="checkbox"/> HHS Press Release <input type="checkbox"/> FDA Talk Paper <input type="checkbox"/> CDER Q&As <input type="checkbox"/> Other

² Answer all questions in all sections in relation to the pending application, i.e., if the pending application is an NDA or BLA supplement, then the questions should be answered in relation to that supplement, not in relation to the original NDA or BLA. For example, if the application is a pending BLA supplement, then a new *RMS-BLA Product Information Sheet for TBP* must be completed.

❖ Exclusivity	
<ul style="list-style-type: none"> Is approval of this application blocked by any type of exclusivity? 	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes
<ul style="list-style-type: none"> NDA and BLAs: Is there existing orphan drug exclusivity for the “same” drug or biologic for the proposed indication(s)? <i>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.</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If, yes, NDA/BLA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 5-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 3-year exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> (b)(2) NDAs only: Is there remaining 6-month pediatric exclusivity that would bar effective approval of a 505(b)(2) application? <i>(Note that, even if exclusivity remains, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date exclusivity expires:
<ul style="list-style-type: none"> NDAs only: Is this a single enantiomer that falls under the 10-year approval limitation of 505(u)? <i>(Note that, even if the 10-year approval limitation period has not expired, the application may be tentatively approved if it is otherwise ready for approval.)</i> 	<input type="checkbox"/> No <input type="checkbox"/> Yes If yes, NDA # and date 10- year limitation expires:
❖ Patent Information (NDAs only)	
<ul style="list-style-type: none"> Patent Information: Verify that form FDA-3542a was submitted for patents that claim the drug for which approval is sought. If the drug is an old antibiotic, skip the Patent Certification questions. 	<input checked="" type="checkbox"/> Verified <input type="checkbox"/> Not applicable because drug is an old antibiotic.
<ul style="list-style-type: none"> 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) <input checked="" type="checkbox"/> Verified 21 CFR 314.50(i)(1) <input type="checkbox"/> (ii) <input type="checkbox"/> (iii)
<ul style="list-style-type: none"> [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). 	<input checked="" type="checkbox"/> No paragraph III certification Date patent will expire
<ul style="list-style-type: none"> [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). <i>(If the application does not include any paragraph IV certifications, mark “N/A” and skip to the next section below (Summary Reviews)).</i> 	<input checked="" type="checkbox"/> N/A (no paragraph IV certification) <input type="checkbox"/> 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?

Yes No

(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)?

Yes No

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 the rest of the patent questions.

If "**No**," continue with question (3).

- (3) Has the patent owner, its representative, or the exclusive patent licensee filed a lawsuit for patent infringement against the applicant?

Yes No

(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) 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)?

Yes No

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 section below (Summary Reviews).

If "**No**," continue with question (5).

<p>(5) Did the patent owner, its representative, or the exclusive patent licensee bring suit against the (b)(2) applicant for patent infringement within 45 days of the patent owner's receipt of the applicant's notice of certification?</p> <p>(Note: This can be determined by confirming whether the Division has received a written notice from the (b)(2) 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).</p> <p><i>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 section below (Summary Reviews).</i></p> <p><i>If "Yes," a stay of approval may be in effect. To determine if a 30-month stay is in effect, consult with the OND ADRA and attach a summary of the response.</i></p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
---	--

CONTENTS OF ACTION PACKAGE

❖ Copy of this Action Package Checklist ³	Yes
Officer/Employee List	
❖ List of officers/employees who participated in the decision to approve this application and consented to be identified on this list (<i>approvals only</i>)	<input checked="" type="checkbox"/> Included
Documentation of consent/non-consent by officers/employees	<input checked="" type="checkbox"/> Included
Action Letters	
❖ Copies of all action letters (<i>including approval letter with final labeling</i>)	Action(s) and date(s) Filing Communication/09-24-2009; Proprietary Name Approval/05-25-2010; Approval/05/27/2010
Labeling	
❖ Package Insert (<i>write submission/communication date at upper right of first page of PI</i>)	
<ul style="list-style-type: none"> • Most recent draft labeling. If it is division-proposed labeling, it should be in track-changes format. 	
<ul style="list-style-type: none"> • Original applicant-proposed labeling 	
<ul style="list-style-type: none"> • Example of class labeling, if applicable 	

³ Fill in blanks with dates of reviews, letters, etc.
Version: 5/14/10

<ul style="list-style-type: none"> ❖ Medication Guide/Patient Package Insert/Instructions for Use (<i>write submission/communication date at upper right of first page of each piece</i>) 	<input type="checkbox"/> Medication Guide <input type="checkbox"/> Patient Package Insert <input type="checkbox"/> Instructions for Use <input checked="" type="checkbox"/> None
<ul style="list-style-type: none"> • Most-recent draft labeling. If it is division-proposed labeling, it should be in ttrack-changes format. 	
<ul style="list-style-type: none"> • Original applicant-proposed labeling 	
<ul style="list-style-type: none"> • Example of class labeling, if applicable 	
<ul style="list-style-type: none"> ❖ Labels (full color carton and immediate-container labels) (<i>write submission/communication date on upper right of first page of each submission</i>) 	
<ul style="list-style-type: none"> • Most-recent draft labeling 	May 26, 2010
<ul style="list-style-type: none"> ❖ Proprietary Name <ul style="list-style-type: none"> • Acceptability/non-acceptability letter(s) (<i>indicate date(s)</i>) • Review(s) (<i>indicate date(s)</i>) 	May 25, 2010 May 24, 2010
<ul style="list-style-type: none"> ❖ Labeling reviews (<i>indicate dates of reviews and meetings</i>) 	<input type="checkbox"/> RPM <input checked="" type="checkbox"/> DMEPA <input type="checkbox"/> DRISK <input type="checkbox"/> DDMAC <input type="checkbox"/> CSS <input checked="" type="checkbox"/> Other reviews DNRD
Administrative / Regulatory Documents	
<ul style="list-style-type: none"> ❖ Administrative Reviews (<i>e.g., RPM Filing Review⁴/Memo of Filing Meeting</i>) (<i>indicate date of each review</i>) ❖ 505(b)(2) Assessment (<i>indicate date</i>) 	RPM Filing Review and Memo of Filing Meeting: 11/13/2009 <input type="checkbox"/> Not a (b)(2)
<ul style="list-style-type: none"> ❖ NDAs only: Exclusivity Summary (<i>signed by Division Director</i>) 	<input checked="" type="checkbox"/> Included
<ul style="list-style-type: none"> ❖ Application Integrity Policy (AIP) Status and Related Documents http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/default.htm 	
<ul style="list-style-type: none"> • Applicant is on the AIP 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
<ul style="list-style-type: none"> • This application is on the AIP <ul style="list-style-type: none"> ○ If yes, Center Director's Exception for Review memo (<i>indicate date</i>) ○ If yes, OC clearance for approval (<i>indicate date of clearance communication</i>) 	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not an AP action
<ul style="list-style-type: none"> ❖ Pediatrics (<i>approvals only</i>) <ul style="list-style-type: none"> • Date reviewed by PeRC <u>March 17 and May 19, 2010</u> If PeRC review not necessary, explain: _____ • Pediatric Page (<i>approvals only, must be reviewed by PERC before finalized</i>) 	<input checked="" type="checkbox"/> Included
<ul style="list-style-type: none"> ❖ Debarment certification (original applications only): verified that qualifying language was not used in certification and that certifications from foreign applicants are cosigned by U.S. agent (<i>include certification</i>) 	<input checked="" type="checkbox"/> Verified, statement is acceptable
<ul style="list-style-type: none"> ❖ Outgoing communications (<i>letters (except action letters), emails, faxes, telecons</i>) 	
<ul style="list-style-type: none"> ❖ Internal memoranda, telecons, etc. 	

⁴ Filing reviews for scientific disciplines should be filed behind the respective discipline tab.
Version: 5/14/10

❖ Minutes of Meetings		
• Regulatory Briefing (<i>indicate date of mtg</i>)		<input checked="" type="checkbox"/> No mtg
• If not the first review cycle, any end-of-review meeting (<i>indicate date of mtg</i>)		<input type="checkbox"/> N/A or no mtg
• Pre-NDA/BLA meeting (<i>indicate date of mtg</i>)		<input type="checkbox"/> No mtg
• EOP2 meeting (<i>indicate date of mtg</i>)		<input type="checkbox"/> No mtg
• Other milestone meetings (e.g., EOP2a, CMC pilots) (<i>indicate dates of mtgs</i>)		
❖ Advisory Committee Meeting(s)		<input checked="" type="checkbox"/> No AC meeting
• Date(s) of Meeting(s)		
• 48-hour alert or minutes, if available (<i>do not include transcript</i>)		
Decisional and Summary Memos		
❖ Office Director Decisional Memo (<i>indicate date for each review</i>)		<input checked="" type="checkbox"/> None
Division Director Summary Review (<i>indicate date for each review</i>)		<input type="checkbox"/> None May 27, 2010
Cross-Discipline Team Leader Review (<i>indicate date for each review</i>)		<input type="checkbox"/> None
PMR/PMC Development Templates (<i>indicate total number</i>)		<input type="checkbox"/> None
Clinical Information⁵		
❖ Clinical Reviews		
• Clinical Team Leader Review(s) (<i>indicate date for each review</i>)		12-28-2009
• Clinical review(s) (<i>indicate date for each review</i>)		12-28-2009
• Social scientist review(s) (if OTC drug) (<i>indicate date for each review</i>)		<input checked="" type="checkbox"/> None
❖ Financial Disclosure reviews(s) or location/date if addressed in another review OR If no financial disclosure information was required, check here <input type="checkbox"/> and include a review/memo explaining why not (<i>indicate date of review/memo</i>)		12-28-2009
❖ Clinical reviews from immunology and other clinical areas/divisions/Centers (<i>indicate date of each review</i>)		<input type="checkbox"/> None DAARP/01-25-2010
❖ Controlled Substance Staff review(s) and Scheduling Recommendation (<i>indicate date of each review</i>)		<input checked="" type="checkbox"/> Not applicable
❖ Risk Management		
• REMS Documents and Supporting Statement (<i>indicate date(s) of submission(s)</i>)		
• REMS Memo(s) and letter(s) (<i>indicate date(s)</i>)		
• Risk management review(s) and recommendations (including those by OSE and CSS) (<i>indicate date of each review and indicate location/date if incorporated into another review</i>)		<input checked="" type="checkbox"/> None
❖ DSI Clinical Inspection Review Summary(ies) (<i>include copies of DSI letters to investigators</i>)		<input type="checkbox"/> None requested

⁵ Filing reviews should be filed with the discipline reviews.
Version: 5/14/10

Clinical Microbiology <input checked="" type="checkbox"/> None	
❖ Clinical Microbiology Team Leader Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Clinical Microbiology Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Biostatistics <input checked="" type="checkbox"/> None	
❖ Statistical Division Director Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Statistical Team Leader Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Statistical Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Clinical Pharmacology <input type="checkbox"/> None	
❖ Clinical Pharmacology Division Director Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
Clinical Pharmacology Team Leader Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None 01-14-2010
Clinical Pharmacology review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None 01-14-2010
❖ DSI Clinical Pharmacology Inspection Review Summary (<i>include copies of DSI letters</i>)	<input type="checkbox"/> None 01-28-2010 and 02-23-2010
Nonclinical <input type="checkbox"/> None	
❖ Pharmacology/Toxicology Discipline Reviews	
• ADP/T Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
• Supervisory Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None 01-05-2010
• Pharm/tox review(s), including referenced IND reviews (<i>indicate date for each review</i>)	<input type="checkbox"/> None 01-05-2010
❖ Review(s) by other disciplines/divisions/Centers requested by P/T reviewer (<i>indicate date for each review</i>)	<input type="checkbox"/> None
❖ Statistical review(s) of carcinogenicity studies (<i>indicate date for each review</i>)	<input checked="" type="checkbox"/> No carc
❖ ECAC/CAC report/memo of meeting	<input checked="" type="checkbox"/> None Included in P/T review, page
❖ DSI Nonclinical Inspection Review Summary (<i>include copies of DSI letters</i>)	<input checked="" type="checkbox"/> None requested
Product Quality <input type="checkbox"/> None	
❖ Product Quality Discipline Reviews	
• ONDQA/OBP Division Director Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None
• Branch Chief/Team Leader Review(s) (<i>indicate date for each review</i>)	<input type="checkbox"/> None 01-04-2010
• Product quality review(s) including ONDQA biopharmaceutics reviews (<i>indicate date for each review</i>)	<input type="checkbox"/> None 01-04-2010
❖ Microbiology Reviews <input type="checkbox"/> NDAs: Microbiology reviews (sterility & pyrogenicity) (OPS/NDMS) (<i>indicate date of each review</i>) <input type="checkbox"/> BLAs: Sterility assurance, microbiology, facilities reviews (DMPQ/MAPCB/BMT) (<i>indicate date of each review</i>)	<input checked="" type="checkbox"/> Not needed
❖ Reviews by other disciplines/divisions/Centers requested by CMC/quality reviewer (<i>indicate date of each review</i>)	<input checked="" type="checkbox"/> None

❖ Environmental Assessment (check one) (original and supplemental applications)	
<input checked="" type="checkbox"/> Categorical Exclusion (<i>indicate review date</i>)(<i>all original applications and all efficacy supplements that could increase the patient population</i>)	12/02/2009
<input type="checkbox"/> Review & FONSI (<i>indicate date of review</i>)	
<input type="checkbox"/> Review & Environmental Impact Statement (<i>indicate date of each review</i>)	
❖ Facilities Review/Inspection	
<input type="checkbox"/> NDAs: Facilities inspections (include EER printout) (<i>date completed must be within 2 years of action date</i>)	Date completed: 09/24/2009 <input checked="" type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation
<input type="checkbox"/> BLAs: TB-EER (<i>date of most recent TB-EER must be within 30 days of action date</i>)	Date completed: <input type="checkbox"/> Acceptable <input type="checkbox"/> Withhold recommendation
❖ NDAs: Methods Validation (<i>check box only, do not include documents</i>)	<input type="checkbox"/> Completed <input type="checkbox"/> Requested <input type="checkbox"/> Not yet requested <input checked="" type="checkbox"/> Not needed

Appendix to Action Package Checklist

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

- (1) It relies on published literature to meet any of the approval requirements, and the applicant does not have a written right of reference to the underlying data. If published literature is cited in the NDA but is not necessary for approval, the inclusion of such literature will not, in itself, make the application a 505(b)(2) application.
- (2) **Or** it relies for approval on the Agency's previous findings of safety and efficacy for a listed drug product and the applicant does not own or have right to reference the data supporting that approval.
- (3) **Or** 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.)

Types of products for which 505(b)(2) applications are likely to be submitted include: fixed-dose combination drug products (e.g., heart drug and diuretic (hydrochlorothiazide) combinations); OTC monograph deviations (see 21 CFR 330.11); new dosage forms; new indications; and, new salts.

An efficacy supplement can be either a (b)(1) or a (b)(2) regardless of whether the original NDA was a (b)(1) or a (b)(2).

An efficacy supplement is a 505(b)(1) supplement if the supplement contains all of the information needed to support the approval of the change proposed in the supplement. For example, if the supplemental application is for a new indication, the supplement is a 505(b)(1) if:

- (1) The applicant has conducted its own studies to support the new indication (or otherwise owns or has right of reference to the data/studies).
- (2) **And** no additional information beyond what is included in the supplement or was embodied in the finding of safety and effectiveness for the original application or previously approved supplements is needed to support the change. For example, this would likely be the case with respect to safety considerations if the dose(s) was/were the same as (or lower than) the original application.
- (3) **And** all other "criteria" are met (e.g., the applicant owns or has right of reference to the data relied upon for approval of the supplement, the application does not rely for approval on published literature based on data to which the applicant does not have a right of reference).

An efficacy supplement is a 505(b)(2) supplement if:

- (1) Approval of the change proposed in the supplemental application would require data beyond that needed to support our previous finding of safety and efficacy in the approval of the original application (or earlier supplement), and the applicant has not conducted all of its own studies for approval of the change, or obtained a right to reference studies it does not own. For example, if the change were for a new indication AND a higher dose, we would likely require clinical efficacy data and preclinical safety data to approve the higher dose. If the applicant provided the effectiveness data, but had to rely on a different listed drug, or a new aspect of a previously cited listed drug, to support the safety of the new dose, the supplement would be a 505(b)(2).
- (2) **Or** the applicant relies for approval of the supplement on published literature that is based on data that the applicant does not own or have a right to reference. If published literature is cited in the supplement but is not necessary for approval, the inclusion of such literature will not, in itself, make the supplement a 505(b)(2) supplement.
- (3) **Or** the applicant is relying upon any data they do not own or to which they do not have right of reference.

If you have questions about whether an application is a 505(b)(1) or 505(b)(2) application, consult with your ODE's ADRA.

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22565

ORIG-1

WYETH
CONSUMER
HEALTHCARE

Advil Congestion Relief

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JANICE Adams

06/09/2010



NDA 022565

**PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE**

Wyeth Consumer Healthcare
5 Giralda Farms
Madison, NJ 07940

ATTENTION: Darcy Gilson
Associate Director, Regulatory Affairs

Dear Ms. Gilson:

Please refer to your New Drug Application (NDA) dated July 28, 2009, received July 28, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ibuprofen and Phenylephrine HCl Tablets, 200 mg/10 mg.

We also refer to your May 10, 2010, correspondence, received May 11, 2010, requesting review of your proposed proprietary name, Advil Congestion Relief. We have completed our review of the proposed proprietary name, Advil Congestion Relief and have concluded that it is acceptable.

If **any** of the proposed product characteristics as stated in your May 10, 2010 submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Catherine Carr, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-2311. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Janice Adams-King at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22565

ORIG-1

WYETH
CONSUMER
HEALTHCARE

ADVIL COLD & SINUS
PE(IBUPROFEN 200MG/PH

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/s/

CAROL A HOLQUIST
05/25/2010



NDA 022565

**PROPRIETARY NAME REQUEST
WITHDRAWN**

Wyeth Consumer Healthcare
5 Giralda Farms
Madison, NJ 07940

ATTENTION: Darcy Gilson
Associate Director, Regulatory Affairs

Dear Ms. Gilson:

Please refer to your New Drug Application (NDA) dated July 28, 2009, received July 28, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ibuprofen and Phenylephrine Hydrochloride Tablets, 200 mg/10 mg.

We acknowledge receipt of your April 22, 2010 correspondence, on April 22, 2010, notifying us that you are withdrawing your [REDACTED] ^{(b) (4)} proposed proprietary name Advil Cold & Sinus PE. This proposed proprietary name request is considered withdrawn as of April 22, 2010.

Please note that if you intend to have a proprietary name for this product, a new request for a proposed proprietary name review should be submitted. (See the Guidance for Industry, *Complete Submission for the Evaluation of Proprietary Names*, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm121568.htm> and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, call Catherine Carr, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-2311. For any other information regarding this application, contact the Office of New Drugs (OND) Regulatory Project Manager, Janice Adams-King at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22565

ORIG-1

WYETH
CONSUMER
HEALTHCARE

ADVIL COLD & SINUS
PE (IBUPROFEN 200MG/PH

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/s/

CAROL A HOLQUIST
05/10/2010

MEMORANDUM OF MEETING MINUTES

MEETING DATE: April 2, 2010
TIME: 1:00 – 2:00 PM EST
LOCATION: Teleconference, WO Bldg 22, Room 4311
APPLICATION: NDA 022565
DRUG NAME: Advil Cold & Sinus PE
TYPE OF MEETING: Guidance Meeting

MEETING CHAIR: Kellie Taylor, Associate Director, DMEPA, OSE

MEETING RECORDER: Catherine Carr, Safety Regulatory Project Manager, OSE

FDA ATTENDEES: (Title and Office/Division)

Office of Surveillance and Epidemiology

Carol Holquist, R.Ph., Director, DMEPA, OSE
Kellie Taylor, Pharm.D. M.P.H., Associate Director, DMEPA, OSE
Tara Turner, Pharm.D., Safety Evaluator, DMEPA, OSE
Chi-Ming Tu, Pharm.D., Safe Medication Management Fellow, DMEPA, OSE
Catherine Carr, M.Sc., Safety Regulatory Project Manager, OSE
Chris Wheeler, Pharm.D., Project Management Team Leader, OSE

EXTERNAL CONSTITUENT ATTENDEES:

Wyeth Consumer Healthcare

Lauren Quinn, J.D. Senior Director, Global Regulatory Affairs
Darcy Gilson, Associate Director, Global Regulatory Affairs
Jeremy Sayles, Senior Product Manager, Marketing
David Schablik, Senior Manager Consumer Insights, Marketing
Jerry Phillips, R.Ph, Drug Safety Institute

BACKGROUND:

Reference is made to RCM # 2009-1591 for the carton and container review and RCM # 2009-1586 for the trade name review for Ibuprofen and Phenylephrine HCl Tablets, 200mg/10mg.

The sponsor submitted a request for proprietary name review for Ibuprofen and Phenylephrine HCl Tablets on August 26, 2009, which was received on August 27, 2009. This product is subject to a pending NDA application with a PDUFA date of May 28, 2010. Upon review of the August 27, 2009 submission, DMEPA concluded that the name ‘Advil Cold & Sinus PE’ was unacceptable and issued a denial letter, dated November 16, 2009.

(b) (4)

MEETING OBJECTIVES:

The purpose of this meeting was to discuss the sponsor's submissions dated, February 17 and March 16, 2010 and to [REDACTED] (b) (4) acceptability of the proposed proprietary name 'Advil Cold & Sinus PE'.

DISCUSSION POINTS:

Following introductions, DMEPA took the opportunity to inform the sponsor that they had reviewed the request [REDACTED] (b) (4) of the proposed name 'Advil Cold & Sinus PE' and wanted to convey their concerns regarding the name. Specifically, DMEPA indicated that the proposed proprietary name 'Advil Cold & Sinus PE' was unacceptable due to the fact that the modifier 'PE' does not sufficiently differentiate between the Advil products containing phenylephrine and pseudoephedrine.

Overall, DMEPA stated the results indicate there is no consistent meaning of the 'PE' modifier among healthcare practitioners or consumers. Therefore, DMEPA concludes that the 'PE' modifier does not provide sufficient differentiation from the currently marketed Advil Cold & Sinus product, which contains pseudoephedrine. Given this data and the fact that the 'PE' modifier has been identified in post-marketing cases of confusion by the Agency and outside organizations, DMEPA [REDACTED] (b) (4) objection to the proposed proprietary name, Advil Cold & Sinus PE, for this product.

[REDACTED] (b) (4)

The sponsor expressed concern regarding the upcoming PDUFA date and [REDACTED] (b) (4)

The sponsor proposed [REDACTED] (b) (4) that they believed were in keeping with the monographed indication for ibuprofen and phenylephrine HCl [REDACTED] (b) (4). DMEPA indicated that a line extension should use nomenclature that is not confusing and has a clear delineation between the Advil products. The name [REDACTED] (b) (4) may not work from a safety perspective since [REDACTED] (b) (4). The [REDACTED] (b) (4) name may be amenable from a safety perspective. However, the sponsor would have to show that consumers would know that “congestion” was different from “cold” as the two products have different ingredients.

[REDACTED] (b) (4)

The sponsor asked whether any advice could be given to them regarding a proprietary name. DMEPA responded that at this point, it is unknown whether there is a modifier that is suitable for products that have very similar ingredients. When a name includes the words “Advil”, “Cold”, and “Sinus”, there is already quite a bit of overlap with the currently marketed Advil Cold & Sinus which can create confusion.

[REDACTED] (b) (4)

DMEPA reminded the sponsor that the OSE PDUFA date for the proposed proprietary name 'Advil Cold & Sinus PE' is May 18, 2010. Because this name has been found to be unacceptable, the sponsor was given the option to voluntarily withdraw their request for reconsideration of the trade name review. DMEPA requested that the sponsor submit revised carton and container labeling reflecting only the established name of the product for review by the team to meet the OND PDUFA date, which is May 28, 2010. The mock carton and container labels should be submitted with the graphics presented as close to the final desired presentation as possible. The sponsor indicated that they plan to continue working on the development of a new proprietary name for the proposed product. If a new proposed proprietary name is submitted prior to the OND PDUFA date, DMEPA will work to expedite the review, within reason, in an effort to meet the OND PDUFA date of May 28, 2010. If the proposed proprietary name is submitted after the OND PDUFA date, the sponsor was advised to submit a request for proprietary name review and a labeling supplement at the same time. It was clarified that OND will approve the labeling supplement and DMEPA will work with OND to take action prior to 120 days.

Prior to concluding the call, DMEPA clarified that there are no requirements to test a proposed proprietary name prior to submission to the Agency for review. The sponsor was also asked to keep DMEPA informed regarding plans for future proprietary name submissions in order to foster open communication on a potential trade name for this product.

ACTION ITEMS:

1. The sponsor will submit revised carton and container labeling reflecting only the established name of the product to the Office of Nonprescription Products.
2. The sponsor will submit correspondence to withdraw the request for reconsideration of the proprietary name submission, dated February 17, 2010.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22565	ORIG-1	WYETH CONSUMER HEALTHCARE	ADVIL COLD & SINUS PE(IBUPROFEN 200MG/PH

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CATHERINE A CARR
05/14/2010

CAROL A HOLQUIST
05/14/2010



NDA 022565

**PROPRIETARY NAME REQUEST
- UNACCEPTABLE**

Wyeth Consumer Healthcare
5 Giralda Farms
Madison, NJ 07940

ATTENTION: Darcy Gilson
Associate Director, Global Regulatory Affairs

Dear Ms. Gilson:

Please refer to your New Drug Application (NDA) dated July 28, 2009, received July 28, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ibuprofen and Phenylephrine HCl Tablets, 200 mg/10 mg.

We also refer to your August 26, 2009, correspondence, received August 27, 2009, requesting review of your proposed proprietary name, Advil Cold & Sinus PE. We have completed our review of this proposed proprietary name and have concluded that this name is unacceptable for the following reasons.

According to your submission, the proposed name, Advil Cold & Sinus PE, was derived from your currently marketed Advil Cold & Sinus product, which contains ibuprofen 200 mg and pseudoephedrine hydrochloride 30 mg. Thus the addition of the "PE" modifier is intended to indicate that the proposed product contains phenylephrine and serve to differentiate the proposed product from the currently marketed pseudoephedrine containing product. However, we are concerned that the 'PE' modifier may not sufficiently differentiate your proposed product from the currently marketed Advil Cold & Sinus product because the modifier 'PE' has been used for products that contain phenylephrine or pseudoephedrine. The literature describes post-marketing cases of confusion between non-prescription products utilizing the 'PE' modifier where the meaning of 'PE' has been misinterpreted as phenylephrine or pseudoephedrine.¹ This confusion has led to medication errors in which patients mistakenly purchased the wrong drug product. Given the documented post-marketing cases of confusion, we are concerned there is no consistent meaning of 'PE' among consumers or healthcare practitioners as to whether this modifier means pseudoephedrine or phenylephrine.

¹ Institute of Safe Medication Practices. Separation Anxiety. Medication Safety Alert! Community/Ambulatory Care Edition. June 2006. Volume 5, Issue 6, Page 3.

Since you have not provided data to support that the 'PE' modifier is not a source of error, we must conclude at this time that the 'PE' modifier is unacceptable for this product. If you choose to pursue this name, you should submit healthcare practitioner and consumer studies that assess the meaning of 'PE' and whether this modifier provides adequate differentiation from the currently marketed Advil Cold & Sinus product.

We scheduled a teleconference for October 28, 2009 to discuss these concerns with you. However, technical difficulties prevented you from participating in this teleconference. We are willing to discuss our concerns further, if requested, following receipt of this letter.

You have not proposed an alternate proprietary name for review. If you intend to have a proprietary name for this product, we recommend that you submit a new request for a proposed proprietary name review. (See the draft Guidance for Industry, *Complete Submission for the Evaluation of Proprietary Names*, [HTTP://www.fda.gov/cder/guidance/7935dft.pdf](http://www.fda.gov/cder/guidance/7935dft.pdf) and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Karen Townsend, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-5413. For any other information regarding this application contact the Office of New Drugs (OND) Regulatory Project Manager, Janice Adams-King at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Carol Holquist, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22565

ORIG-1

WYETH
CONSUMER
HEALTHCARE

ADVIL COLD & SINUS
PE(IBUPROFEN 200MG/PH

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/s/

CAROL A HOLQUIST
11/16/2009

Adams-King, Janice

From: Gilson Darcy [gilsond@wyeth.com]
Sent: Monday, October 26, 2009 11:35 AM
To: Adams-King, Janice
Cc: Archives_Administrator@wyeth.com
Subject: Re: Information Request: NDA 22-565/Advil Cold & Sinus PE
Attachments: 1.4.1.2 Letter of Authorization_(b)(4)_8140.pdf; 1.4.1.3 Letter of Authorization_(b)(4) Packaging_6684.pdf; 1.4.1.4 Letter of Authorization_(b)(4)3764.pdf; 1.4.1.5 Letter of Authorization_(b)(4)984.pdf; 1.4.1.6 Letter of Authorization_(b)(4)_994535.pdf; 1.1.2 FDA Form 356h.pdf; 1.2 Cover Letter.pdf; 1.4 References.doc; 1.4.1.1 Letter of Authorization_(b)(4)_8709.pdf

Hi Janice,

Wanted to let you know that we submitted a response to the CMC questions outlined in your email through the Gateway on Friday, October 23, 2009.

I am attaching a copy of the amendment to this email in case you haven't received it yet.

Please let me know if you have any questions or need any additional information.

Thanks,

Darcy

Darcy Gilson
Wyeth Consumer Healthcare
Five Giralda Farms
Madison, NJ 07940

973 660 6975
973 660 7187 fax

Before printing this e-mail, please consider the environment.

>>> "Adams-King, Janice" <Janice.Adams-King@fda.hhs.gov> 10/16/2009 2:11 PM >>>

Good Afternoon Darcy,

We are in the process of reviewing the above-referenced NDA and would appreciate your prompt attention to the following:

1. Clarify if there is any Chemistry, Manufacturing, Controls information which is different from that in NDA 22-112.
2. Provide updated Letters of Authorization for all referenced DMFs.
3. Clarify the purpose of the (b)(4) since your proposed carton package SKU's are for multiples of 10 caplets."

Thank you, Janice

CDR Janice Adams-King, RN, BSN, MS (USPHS)
Regulatory Project Manager
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products, CDER/FDA
10903 New Hampshire Avenue, Bldg. 22, Room 5483
Silver Spring, MD 20993
Phone: 301-796-3713 Fax: 301-796-9899
Janice.Adams-King@fda.hhs.gov

Adams-King, Janice

From: Gilson Darcy [gilsond@wyeth.com]
Sent: Tuesday, October 27, 2009 5:27 PM
To: Adams-King, Janice
Subject: Re: Information Request: NDA 22-565/Advil Cold & Sinus PE(PK/PD Analysis Report)
Attachments: Cover Letter NDA 22-565 10.26.2009_1.doc; 1.1.2 FDA Form 356h.pdf; 2.5 Clinical Overview (Updated).doc; Description of Files.doc; Clinical Application of PKPD modeling.doc; AI-07-02 Ibuprofen Final Data 10July2008.xls; Modeling of Ibuprofen in Dental Pain PKPD Analysis Report.pdf; Define.pdf; demo2.XPT; eff.dnt2.XPT; IBU_PK.XPT; ibuprofen pkpd modeling v1.3.txt; mod01.out.txt; panrelief.nm.input.csv; prt8.out.txt; Requested Info PKPD.doc

Hi Janice,

Thanks for the email, we have included the correct graph in our response to your email request of 10/19/2009 attached. We will also be submitting via the gateway.

Some of the data files with the .XML extension require the SAS viewer to open.

Please let me know if you need any other information or have questions.

Thanks,

Darcy

Darcy Gilson
Wyeth Consumer Healthcare
Five Giralda Farms
Madison, NJ 07940

973 660 6975
973 660 7187 fax

Before printing this e-mail, please consider the environment.

>>> "Adams-King, Janice" <Janice.Adams-King@fda.hhs.gov> 10/19/2009 11:46 AM >>>

Good Morning Darcy,

For The Report "Modeling of Ibuprofen in Dental Pain (PK/PD Analysis Report)" please submit the following by Monday, October 26, 2009.

All datasets used for model development and validation should be submitted as a SAS transport files (*.xpt). A description of each data item should be provided in a Define.pdf file. Any concentrations and/or subjects that have been **excluded from the analysis** should be flagged and maintained in the datasets.

Model codes or control streams and output listings should be provided for all major model building steps, e.g., base structural model, covariates models, final model, and validation model. These files should be submitted as ASCII text files with *.txt extension (e.g.: myfile_ctl.txt, myfile_out.txt).

A model development decision tree and/or table which gives an overview of modeling steps.
For the population analysis reports we request that you submit, in addition to the standard model diagnostic plots, individual plots for a representative number of subjects. Each individual plot should include observed concentrations, the individual

5/24/2010

Adams-King, Janice

From: Gilson Darcy [gilsond@wyeth.com]
Sent: Tuesday, December 01, 2009 3:04 PM
To: Adams-King, Janice
Subject: Re: Information Request: NDA 22565/Advil Cold & Sinus
Attachments: FDA Form 356h28b309fd.pdf; Cover Letter.doc; AQ0813.zip; AQ0812.zip

Hi Janice,

Got your email. Please see the attached letter, Form, and requested files. We plan to submit through the gateway tomorrow.

Please let me know if you have any questions or need any additional information.

Darcy

Darcy Gilson
Wyeth Consumer Healthcare
Five Giralda Farms
Madison, NJ 07940

973 660 6975
973 660 7187 fax

Before printing this e-mail, please consider the environment.

>>> "Adams-King, Janice" <Janice.Adams-King@fda.hhs.gov> 11/24/2009 10:14:13 AM >>>

Darcy,

Please provide PK data as SAS transport files that should also include treatment, sequence, period, subject number for studies AQ-08-13 and study AQ-08-12 as soon as possible. Thank you, Janice

CDR Janice Adams-King, RN, BSN, MS (USPHS)
Regulatory Project Manager
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products, CDER/FDA
10903 New Hampshire Avenue, Bldg. 22, Room 5483
Silver Spring, MD 20993
Phone: 301-796-3713 Fax: 301-796-9899
Janice.Adams-King@fda.hhs.gov

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22565

ORIG-1

WYETH
CONSUMER
HEALTHCARE

Advil Congestion Relief

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/s/

JANICE Adams
06/01/2010



NDA 22-565

FILING COMMUNICATION

Wyeth Consumer Healthcare
Attention: Erica Sinclair, MBA
Senior Manager, Global Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Sinclair:

Please refer to your new drug application (NDA) dated July 28, 2009, received July 28, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Advil® Cold & Sinus PE (ibuprofen 200 mg/phenylephrine HCl 10 mg) caplets.

We also refer to your submissions dated August 7, 13, and 27, 2009 and September 3 and 18, 2009.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Therefore, this application is considered filed 60 days after the date we received your application in accordance with 21 CFR 314.101(a). The review classification for this application is **Standard**. Therefore, the user fee goal date is May 28, 2010.

We are reviewing your application according to the processes described in the Guidance for Review Staff and Industry: Good Review Management Principles and Practices for PDUFA Products. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing commitment requests by January 15, 2010.

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

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We acknowledge your request for a waiver of pediatric studies for the (b) (4) old age group for this application. It has been determined that pediatric studies are required under PREA for this NDA product. Please submit a pediatric plan for the Agency's review.

If you have any questions, call Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22565	ORIG-1	WYETH CONSUMER HEALTHCARE	ADVIL COLD & SINUS PE(IBUPROFEN 200MG/PH

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/s/

ANDREA LEONARD SEGAL
10/09/2009



NDA 22-565

FILING COMMUNICATION

McNeil Consumer Healthcare
Attention: Erica Sinclair, MBA
Senior Manager, Global Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Sinclair:

Please refer to your new drug application (NDA) dated July 28, 2009, received July 28, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, for Advil® Cold & Sinus PE (ibuprofen 200 mg/phenylephrine HCl 10 mg) caplets.

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We acknowledge your request for a waiver of pediatric studies for the (b) (4) old age group for this application. It has been determined that pediatric studies are required under PREA for this NDA product. Please submit a pediatric plan for the Agency's review.

If you have any questions, call Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22565

ORIG-1

WYETH
CONSUMER
HEALTHCARE

ADVIL COLD & SINUS
PE(IBUPROFEN 200MG/PH

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/s/

ANDREA LEONARD SEGAL

09/24/2009



NDA 22-565

NDA ACKNOWLEDGMENT

Wyeth Consumer Healthcare
Attention: Erica Sinclair, MBA
Senior Manager, Global Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Sinclair:

We have received your new drug application (NDA) submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product: Advil[®] Cold & Sinus PE (ibuprofen 200 mg and phenylephrine HCl 10 mg) capsules

Date of Application: July 28 2009

Date of Receipt: July 28, 2009

Our Reference Number: NDA 22-565

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 September 26, 2009 in accordance with 21 CFR 314.101(a).

If you have not already done so, promptly submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>. Failure to submit the content of labeling in SPL format may result in a refusal-to-file action under 21 CFR 314.101(d)(3). The content of labeling must conform to the content and format requirements of revised 21 CFR 201.56-57.

The NDA number provided above should be cited at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Nonprescription Clinical Evaluation
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, please see <http://www.fda.gov/cder/ddms/binders.htm>.

If you have any questions, call Janice Adams-King, Regulatory Project Manager, at (301)796-3713.

Sincerely,

{See appended electronic signature page}

Janice Adams-King
Regulatory Project Manager
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-22565

ORIG-1

WYETH
CONSUMER
HEALTHCARE

ADVIL COLD & SINUS
PE(IBUPROFEN 200MG/PH

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/s/

JANICE Adams

09/04/2009

Form Approved: OMB No. 0910 - 0297 Expiration Date: January 31, 2010 See instructions for OMB Statement, below.					
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 WYETH CONSUMER HEALTHCARE Darcy Gilson 5 GIRALDA FARMS MADISON NJ 07940-0871 US	4. BLA SUBMISSION TRACKING NUMBER (STN) / NDA NUMBER 22-565				
2. TELEPHONE NUMBER 973-660 6975	5. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL? <input checked="" type="checkbox"/> YES <input type="checkbox"/> 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: <input checked="" type="checkbox"/> THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION <input type="checkbox"/> THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO:				
3. PRODUCT NAME Ibuprofen 200 mg/Phenylephrine 10 mg	6. USER FEE I.D. NUMBER PD3009466				
7. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.					
<input type="checkbox"/> A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT BEFORE 9/1/92 (Self Explanatory)					
<input type="checkbox"/> A 505(b)(2) APPLICATION THAT DOES NOT REQUIRE A FEE					
<input type="checkbox"/> THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(E) of the Federal Food, Drug, and Cosmetic Act					
<input type="checkbox"/> THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALY					
8. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO					
OMB Statement: Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, 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: <table style="width:100%; border: none;"> <tr> <td style="width: 33%;"> Department of Health and Human Services Food and Drug Administration CBER, HFM-99 1401 Rockville Pike Rockville, MD 20852-1448 </td> <td style="width: 33%;"> Food and Drug Administration CDER, HFD-94 12420 Parklawn Drive, Room 3046 Rockville, MD 20852 </td> <td style="width: 33%;"> An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. </td> </tr> </table>			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	An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.
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	An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.			
SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE 	TITLE ASSOCIATE DIRECTOR GLOBAL REGULATORY AFFAIRS	DATE 7-24-2009			
9. USER FEE PAYMENT AMOUNT FOR THIS APPLICATION \$0.00					
Form FDA 3397 (03/07)					

[Close](#) [Print Cover sheet](#)

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

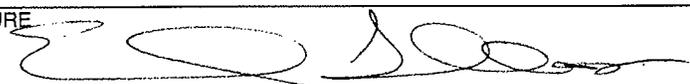
With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	(b) (4)	

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Emanuel Troullos, DMD	TITLE Senior Director Clinical Research
FIRM/ORGANIZATION Wyeth Consumer Healthcare	
SIGNATURE 	DATE 06/26/2009

Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
5600 Fishers Lane, Room 14C-03
Rockville, MD 20857