CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-146

Correspondence

Printed by Stephen Fredd

Electronic Mail Message

nsitivity: COMPANY CONFIDENTIAL

Date: 10-Jul-2000 09:45pm
From: Lee, Jessie APX
LEEJ@HPD.Abbott.com
Dept:
Tel No:

): 'Stephen Fredd 301-594-5300 FAX 301 (FREDD@A1)

ıbject: Re: NDA 21-146

. Fredd,

have moved to TAP Pharmaceutical Products. Today is my first day in TAP.
›rry that I did not had a chance to inform you about my transfer last week.

›u request has been forwarded to Mr. Jonathan Dohnalek who took over this
›A in regulatory affairs. I also forwarded your request to Ms. Melissa
.rthen and Dr. Tom Willer who will assist Jonathan in sending the requested
ıformation to you as soon as possible.

there are any further questions, Please contact Mr. Dohnalek at (847)
;7-3413.

's been a pleasure working with you. Hope the atropine medical review is
tisfactory and the NDA can be expeditiously approved.

ıain, thanks for all your help.

ıssie

----Original Message-----
om: Stephen Fredd 301-594-5300 FAX 301-594-5494
ıailto:FREDD@cder.fda.gov]
nt: Monday, July 10, 2000 2:42 PM
ı: LEEJ@hpd.abbott.com
ıbject: NDA 21-146
ınsitivity: Confidential

›uld it be possible for me to get a diskette of the proposed atropine
ılfate labeling. I need it in word format.
ank you.

ABBOTT

ORIGINAL

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

April 6, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH
DIV. OF CARDIO-RENAL DRUG PRODUCTS, HFD #110
Attn: DOCUMENT CONTROL ROOM
5600 Fishers Lane
Rockville, Maryland 20857

ATTENTION: Raymond Lipicky, M.D.
Director

VIA FAX (301) 594-5495
(paper copy via mail)

GENERAL CORRESPONDENCE

RE: **FDA-ABBOTT Teleconference - Meeting Minutes**
NDA 21-146 Atropine Sulfate Injection, USP in Plastic Syringe
(Submitted December 16, 1999 by Abbott Laboratories)

NEW CORRESP
(NC)

Date: April 6, 2000, 12 Noon Eastern Day Light Saving Time

Meeting Attendees:

FDA:	Stephen Fredd, M.D.	Deputy Director for Policy, HFD-110
ABBOTT:	Thomas Willer, Ph.D.	Associate Director, Regulatory Affairs
	Melissa Warthen, R.N.	Medical Affairs
	Jessie Lee, Ph.D.	Manager, Regulatory Affairs

Background

This meeting was the second follow-up meeting for the Abbott-FDA conference of February 16, 2000 concerning literature references supportive of the product's indications. The Agency offered to work with Abbott to identify the adequacy of an approach to finding literature references via various medical databases. The teleconference covered the following major points.

Medical Literature Search

At the beginning of the meeting, Ms. Melissa Warthen summarized the effort in conducting the medical literature search. She did searches on medical textbooks, various medical databases and obtained about 10,000 hits ("Atropine"). Among all the hits, only about forty journal articles and textbook references contained clinical information sufficient in support of the proposed medical indications for Atropine Sulfate Injection.

Dr. Fredd suggested also researching pharmacology studies in support of any insert changes. Abbott Laboratories will conduct further literature search on the pharmacology studies with Atropine.

ORIGINAL

Submission Outline

Once all literature articles are obtained and reviewed by Abbott Laboratories, Dr. Fredd suggested that the information be organized with reference material in the following outline:

1. Pharmacology studies references
2. Specific information to support medical indications
3. Literature to support the dosage, administration and routes
4. Pediatric information
5. Annotated proposed package insert

He recommended that this clinical package be submitted as a single submission with a complete write-up and reference materials.

Action Plan

FDA and Abbott will continue teleconferencing when needed. Abbott Laboratories will compile the medical information as outlined above for FDA review in the near future.

ABBOTT LABORATORIES

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
FAX: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

JYL:jl

ORIGINAL

ABBOTT

Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

March 24, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH
DIV. OF CARDIO-RENAL DRUG PRODUCTS, HFD #110
Attn: DOCUMENT CONTROL ROOM
5600 Fishers Lane
Rockville, Maryland 20857

ATTENTION: Stephen Fredd, M.D.
Deputy Director

CC: Ms. Natalia Morgenstern

VIA FAX (301) 594-5495

GENERAL CORRESPONDENCE

NEW CORRESP
(NC)

RE: **FDA-ABBOTT Teleconference - Meeting Minutes**
NDA 21-146 Atropine Sulfate Injection, USP in Plastic Syringe
(Submitted December 16, 1999 by Abbott Laboratories)

Date: March 24, 2000, 12 Noon Eastern Standard Time

Meeting Attendees:

FDA:	Stephen Fredd, M.D.	Deputy Director for Policy, HFD-110
ABBOTT:	Thomas Willer, Ph.D.	Associate Director, Regulatory Affairs
	Melissa Warthen, R.N.	Medical Affairs
	Jessie Lee, Ph.D.	Manager, Regulatory Affairs

Background

This meeting is a follow-up for the Abbott-FDA conference of February 16, 2000 concerning literature references supportive of the product's indications. The Agency offered to work with Abbott to identify the adequacy of an approach to finding literature references via various medical databases. The teleconference covered the following major points.

Medical Literature for Indications

At the beginning of the meeting, Dr. Fredd referred to the insert labeling of the approved NDA for ATROPEN® containing relevant information for treatment of toxic exposure to organophosphorous or carbamate insecticides. This clinical information can be referenced in the Atropine NDA which is also indicated for organophosphorous gas poison and other uses. (After the teleconference Dr. Fredd faxed this insert to Dr. Jessie Lee; 3/24/00.) Dr. Fredd stated that the Agency already had approved ATROPEN® and Abbott could use references therein to support this indication. For the other indications he suggested referring to 21 CFR 314.54(a) in order to obtain approval for additional indications. 21 CFR 314.54(a) provides a procedure for submission of application requiring investigations for approval of a new indication for a listed drug.

ORIGINAL

Dr. Fredd stated that well controlled clinical studies are required to support the medical indications. He requested that this information be well organized with reference material to support each requested indication of the product. This clinical package should be submitted as a single submission with a complete write-up and reference materials.

Other Issues: Pediatric Labeling

Dr. Fredd questioned if Abbott was seeking approval for pediatric usage since ATROPEN was not indicated for infants. Abbott needs to determine the uses, doses and routes of administration for Atropine Sulfate Injection and provide information to support them.

New Indications

Dr. Fredd agreed that Abbott should include any indications that are currently used in medical practice. Charlie McLeskey, Medical Director, Abbott Laboratories, has already identified three such indications. Dr. Fredd agreed to review this approach.

Action Plan

FDA and Abbott will teleconference again on April 6, 2000, 12:00 - 1:00 pm (Eastern day light saving time), 11:00 am - 12:00 pm (Central day light saving time). Abbott will prepare additional literature search data and report its progress to the Agency for guidance and focus. Abbott will call Dr. Fredd.

ABBOTT LABORATORIES

Jessie Y. Lee

Jessie Y. Lee, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 937-5513
FAX: (847) 938-7867
e-Mail: LEEJ@hpd.abbott.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-146

JAN 3 - 2000

Abbott Laboratories
Attention: Jessie Y. Lee, Ph.D.
200 Abbott Park Road, D-389, AP30
Abbott Park, IL 60064-6157

Dear Dr. Lee:

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: Atropine Sulfate Injection, USP, Plastic Syringe, 0.1 mg/mL (5 and 10 mL) and 0.05 mg/mL (5 mL)

Therapeutic Classification: Standard (S)

Date of Application: December 16, 1999

Date of Receipt: December 20, 1999

Our Reference Number: NDA 21-146

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on February 18, 2000 in accordance with 21 CFR 314.101(a).

As of April 1, 1999, 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 (63 FR 66632).

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR).

FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsor should obtain a Written Request before submitting pediatric studies to an NDA. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

Under 21 CFR 314.102(c) of the new drug regulations, you may request an informed conference with this division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the application's ultimate approvability. Alternatively, you may choose to receive such a report by telephone.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Division Document Room, HFD-110
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Attention: Division Document Room, HFD-110
1451 Rockville Pike
Rockville, Maryland 20852-1420

If you have any questions, please call:

Ms. Diana Willard
Regulatory Project Coordinator
301-594-5311

Sincerely yours,

/S/

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 6, 1998

Thomas F. Willer, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Abbott Laboratories
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, IL 60064-3537

Dear Dr. Willer:

This letter is in response to your inquiry regarding the regulatory requirements that should be followed to gain marketing approval for changing certain parenteral drug products from glass to plastic syringe containers. See also the attached letter dated September 3, 1996, in which Roger Williams, M.D. addressed a similar matter for your attention.

After careful consideration, we have the following observations:

1. Drug products contained in plastic are deemed by regulation to be "new drugs". See 21 CFR 310.502 (a) (10) and 310.509 (a). The "new drug" status of parenteral drug products in plastic containers applies to both large and small volume products. Id.; see also CDER MAPP 6020.2 "Applications for Parenteral Products in Plastic Immediate Containers" (copy of MAPP enclosed).

2. As "new drugs", such products can only be introduced or delivered for introduction into interstate commerce if they are the subject of an approved application filed under section 505(b) or 505(j) of the Federal Food, Drug and Cosmetic Act.

3. For each of the products under discussion, an abbreviated application may be filed under section 505(j) if a "listed drug" as defined in section 505(j)(7) can be identified for the drug product. It is our understanding that there are no "listed drugs" for the products you are seeking to market.

4. Therefore, to gain the necessary market approval for the drug products under discussion, you would be expected to file an application under section 505(b) of the Act. Based on your description of the products, including the apparent substantial marketing history, you should consider whether an application under section 505(b)(2), which may sometimes may consist of simple literature/medical textbook

information to support safety and efficacy, may be feasible for each of these drug products.

If you have any questions or comments concerning this matter please contact Ms. Patricia DeSantis, Drug Review Program Director, by phone at (301) 594-5400.

Sincerely,

/S/

Murray M. Lumpkin, M.D.
Deputy Center Director (Review Management)
Center for Drug Evaluation and Research

Enclosures

REVIEW MANAGEMENT

APPLICATIONS FOR PARENTERAL PRODUCTS IN PLASTIC IMMEDIATE CONTAINERS

CONTENTS

PURPOSE

This MAPP describes the types of new drug application that will satisfy the requirements in 21 CFR 310.509(a) for a new drug application for approval of any parenteral drug product to be packaged in a plastic immediate container.

BACKGROUND

The Code of Federal Regulations, Title 21, Section 310.509(a) established that any parenteral drug product packaged in a plastic immediate container is a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and requires an approved new drug application as a condition for marketing. Section 310.509 took effect when 505(b) was the only provision in the FD&C Act for submission of a new drug application. The subsequent enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman-Hatch Amendments) replaced 505(b) with 505(b)(1), 505(b)(2) and 505(j), thereby creating three distinct types of applications for approval of new drugs depending on the nature and the source of the evidence required to demonstrate the safety and effectiveness of the new drug product.

REFERENCES

- 21 CFR 310.509 Parenteral Drug Products in Plastic Containers
- 21 CFR 314.3 Definitions

DEFINITIONS

- **Application.** As defined under 21 CFR 314.3, includes all amendments and supplements to the application.
- **Parenteral Drug Product.** A sterile solution intended for administration by injection, internal irrigation, or for use in dialysis procedures.
- **Small Volume Parenteral** (SVP). A parenteral drug product packaged in a volume of less than 100 mL.
- **Large Volume Parenteral** ((LVP). A parenteral product packaged in a volume of 100 mL or more.
- **Limited Confirmatory Testing.** Simple studies intended to rule out unlikely problems. In some cases limited confirmatory testing may include acute animal studies. However, a study to answer basic safety or effectiveness questions or a study that would require substantial scientific review would not be considered limited confirmatory testing.

POLICY

- The requirements for a "new drug application" under 21 CFR 314.509(a) may be satisfied by a new drug application (NDA) submitted in accordance with section 505(b)(1) or section 505(b)(2), an abbreviated new drug application (ANDA) submitted in accordance with section 505(j) or, for antibiotics, an NDA or abbreviated antibiotic application (AADA) submitted in accordance with section 507 of the FD&C Act, or by a supplement to a previously approved application of one of these types.
- An application for approval of a parenteral product in a plastic immediate container may be filed as an ANDA under section 505(j) or, for antibiotics, an AADA under section 507 provided that, 1) the product duplicates an approved product listed in the current edition of *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book") and 2) approval of the product in the plastic immediate container does not require studies beyond limited confirmatory testing and the testing described in the USP.
- An application for approval of a parenteral product in a plastic immediate container for which the container requires animal studies beyond limited confirmatory testing and the testing described in the USP to show that the drug

product is safe must be submitted as an NDA under section 505(b) or, for antibiotics, under section 507.

- An application for approval of a parenteral product in a plastic immediate container containing an active ingredient or a combination of active ingredients not previously approved under an application submitted under section 505(b) or section 507, including an application for a product currently marketed in a glass container for which there is no reference listed drug, should be filed as an NDA under section 505(b) or 507 (as appropriate).

    1. Applications filed for approval of new drugs under 505(b) and non-abbreviated applications under 507 are required to contain evidence of safety and effectiveness. Published reports may be adequate for certain applications. However, reference to general recognition of safety and effectiveness is an inadequate basis for approval of a new drug.

    2. Applications filed under 505(b) or 507 for parenteral products in plastic containers that meet the definition of a "human drug application" in the Prescription Drug User Fee Act of 1992 (PDUFA) are subject to user fees.

- This policy applies to both large volume parenteral products and small volume parenteral products.

- This policy applies to applications for parenteral products packaged in plastic immediate containers regardless of whether the plastic material has been previously used to package an approved drug product.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP - 3 1996

Thomas F. Willer, Ph.D.
Manager, Regulatory Affairs
Hospital Products Division
Abbott Laboratories
Dept. 389, AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-3537

RE: Applications for Products in New Plastic Syringes

Dear Dr. Willer:

This responds to your inquiry to Dr. Marilyn Apfel concerning the types of applications that should be submitted for approval of certain drug products that you propose to package in prefilled syringes made of a new plastic material.

We have applied the following general policies in reaching the decisions outlined below for each individual product:

1. Applications for approval of small volume parenteral (SVP) products to be packaged in new plastic syringes may be submitted as ANDAs under section 505(j) or AADAs under section 507 of the Federal Food, Drug, and Cosmetic (FD&C) Act if there is an approved reference listed drug product in the current edition of the publication Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), and provided that approval of the product does not require studies beyond limited confirmatory testing. Limited confirmatory testing means simple studies intended to rule out unlikely problems. In some cases limited confirmatory testing may include acute animal studies. However, a study to answer basic safety or effectiveness questions or a study that would require substantial scientific review would not be considered limited confirmatory testing. If there are toxicology issues associated with the new previously unapproved plastic that require animal studies beyond limited confirmatory testing or the testing described in the USP to show that the drug product is safe, then an abbreviated application under section 505(j) or section 507 is not appropriate, and an NDA or supplement under section 505(b) or section 507 should be submitted. The concentration and total volume of the proposed product must be the same as for the approved product.

2. If you have an approved ANDA for a product packaged in vials or ampules, a separate ANDA is required for approval of that product packaged in a prefilled syringe.

3. Separate ANDAs are required for each container material (glass and plastic).

4. If Abbott holds an approved NDA for the same product in a different container, a supplement to the NDA should be submitted for the product in the new plastic syringe.

We have reviewed the list of products you provided to Dr. Marilyn Apfel in your October 31, 1994, letter. We have added , Injection, , and Verapamil Hydrochloride Injection, USP, 10 mg/mL, to the list based on your February 15, 1996, telephone conversation with Mr. Thomas Hassall. We have separated the products into three groups: 1) products for which Abbott currently holds an approved NDA or ANDA for marketing the products in a vial or in a prefilled syringe made of either glass or a different plastic material; 2) products for which Abbott does not currently have approved NDAs or ANDAs but for which a reference listed drug exists; and 3) products for which there is no approved reference listed drug. Our conclusions concerning the appropriate type of application to be submitted for each product you proposed are summarized below. ANDAs may be submitted, where recommended, below provided there are no toxicology issues associated with the new plastic that require animal studies beyond limited confirmatory testing or the testing described in the USP to show that the product is safe.

1. Products for which Abbott holds approved NDAs or ANDAs:

a. Bretylium Tosylate Injection, USP, 50 mg/mL

Abbott's NDA 19-030 is approved for marketing Bretylium Tosylate Injection, USP, 50 mg/mL in a 10 mL, plastic vial. The proposed product in the new plastic syringe should be submitted as a supplemental application to this NDA.

b. Furosemide Injection, USP, 10 mg/mL

Your application, number 18-667, is an ANDA under which you have approval to market Furosemide Injection, USP, 10 mg/mL, in prefilled glass syringes. Under present policy, you should submit a separate ANDA for approval of Furosemide Injection, USP in the new plastic syringe.

c. Lidocaine HCl Injection, USP 1%

ANDA 88-299 is approved for marketing Lidocaine HCl Injection, USP 1% in 20 mL, 30 mL, and 50 mL plastic vials. A separate ANDA should be submitted for approval of Lidocaine HCl Injection, USP, 1% in the new prefilled plastic syringe.

d. Lidocaine HCl Injection, USP 2%

ANDA 83-158 provides for marketing this product in the Abboject® glass syringe and the "Universal Additive Syringe," also a glass package. Because the proposed product is to be packaged in a plastic syringe, our present policy requires you to submit a new ANDA.

e. Sodium Chloride Injection, USP, 0.9%

Abbott's NDA 19-218 is approved for marketing 0.9% Sodium Chloride Injection, USP, in plastic syringes. You should submit a supplemental application to NDA 19-218 for the proposed product in the new plastic syringe.

f. Sterile Water for Injection

Abbott's NDA 18-801 is approved for marketing Sterile Water for Injection in 10 mL, 20 mL, and 50 mL plastic vials. You should submit a supplement to NDA 18-801 for approval of Sterile Water for Injection in the new plastic syringe.

g. Verapamil Hydrochloride Injection, USP, 2.5 mg/mL

You currently have approved ANDAs for Verapamil Hydrochloride Injection, USP, 2.5 mg/mL in glass vials, glass ampules, and glass syringes. If you intend to replace the glass syringe with the new plastic syringe you may submit a supplement for the new container closure system to the ANDA for the glass syringe. If you intend to add the product packaged in the new plastic syringe to your existing product line, you must submit a new ANDA.

2. Products for which Abbott does not have approved NDAs or ANDAs but for which a reference listed drug exists:

a.

In your telephone conversation with Mr. Thomas Hassall on February 15, 1996, you noted that the largest volume of any strength of [redacted] to be packaged in the new syringe would be [redacted].

This product is eligible for submission under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Therefore, Abbott may submit an ANDA for approval to market it in the new plastic prefilled syringe provided the product you propose to market otherwise meets the requirements for submission under section 505(j) of the FD&C Act.

b.

This product is eligible for submission under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Therefore, Abbott may submit an ANDA for approval to market it in the new plastic prefilled syringe provided the product you propose to market otherwise meets the requirements for submission under section 505(j) of the FD&C Act.

3. Products for which there is no approved reference listed drug:

Because there appear to be no approved NDAs for the solutions in the products listed below and, therefore, no "reference listed drug," approval under section 505(b) of the FD&C Act is required prior to marketing them in the new plastic prefilled syringe. In the case of [redacted] a supplement or supplements may be submitted as explained below.

a.

There is no listed drug in the Orange Book for either of these strengths of Atropine Sulfate Injection, USP.

b.

c.

Abbott has an approved NDA for Dextrose 50% Injection in a plastic Abboject® syringe (NDA 19-445) but not for . Section IIB of FDA's interim guidance document dated July 12, 1993, "Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees Under the Prescription Drug User Fee Act of 1992," addresses the kinds of changes to an approved NDA that may be submitted as supplements. It states that changes based on chemistry, manufacturing or controls data that change the strength or concentration should be submitted as supplements [section II(B)(2)]. Therefore, Dextrose Injection, USP, . in the new syringe may be submitted as a supplement to NDA 19-445. The guidance also directs the submission of supplements for requests for approval of a new indication or a modification of a previously approved indication [section II(B)(3)]. If the product bears a different indication (for example, use for a different condition or population with different recommendations pertaining to dose or dosage regimen), a separate efficacy supplement supported by appropriate clinical data would also be required. An efficacy supplement that requires clinical data as defined in the PDUFA would normally be subject to an application fee under the Prescription Drug User Fee Act of 1992 (PDUFA).

The applications in group three would be expected to be subject to user fees under the PDUFA.

If you have any questions with respect to these recommendations, please contact Dr. Marilyn Apfel at (301) 594-5460.

Sincerely,

/S/

Roger L. Williams, M.D.
Deputy Center Director for Pharmaceutical Science
Center for Drug Evaluation and Research