



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 8 2002

Food and Drug Administration  
Rockville MD 20857

Thomas A. Gerding  
Director, Regulatory Affairs  
GlaxoSmithKline  
Five Moore Drive  
P.O. Box 13398  
Research Triangle Park, NC 27709

3066 '02 JUL 10 P1:16

Re: Docket No. 99P-0389/CP1

Dear Mr. Gerding:

This letter responds to your citizen petition dated March 3, 1999, concerning a draft guidance for industry on topical dermatological drug products.

In the *Federal Register* of June 18, 1998 (63 FR 33375), the Food and Drug Administration (FDA) announced the availability of a draft guidance entitled *Topical Dermatological Drug Product NDAs and ANDAs — In Vivo Bioavailability, Bioequivalence, In Vitro Release, and Associated Studies*. The draft guidance represented the Agency's thinking at that time on bioavailability and bioequivalence approaches for topical dermatological drug products. The purpose of the draft guidance was to provide recommendations to sponsors of new drug applications, abbreviated new drug applications, and supplements on the performance of bioavailability and bioequivalence studies for topical dermatological drug products. The draft guidance proposed methods to establish bioavailability and bioequivalence, including (1) clinical studies, (2) pharmacodynamic studies, (3) dermatopharmacokinetic studies, and (4) in vitro studies.

You request in your petition that FDA not approve abbreviated new drug applications for topical dermatological drug products based on the principles for establishing bioequivalence (specifically DPK studies) outlined in the draft guidance.

In the *Federal Register* of May 17, 2002 (67 FR 35122, copy enclosed), the FDA issued a notice withdrawing the draft guidance based on concerns raised in comments and at an advisory committee meeting about the adequacy of the DPK method to assess bioequivalence and the reproducibility of the method. In light of this action, your petition has been effectively granted.

Sincerely yours,

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research

Enclosure

99P-0389

PAV1

Dated: May 7, 2002.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 02-12360 Filed 5-16-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00D-0084]

#### Guidance for Industry on Special Protocol Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Special Protocol Assessment." This guidance provides guidance for industry on procedures adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, FAX 888-CBERFAX or 301-827-3844. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Kim M. Colangelo, Center for Drug Evaluation and Research (HFD-2), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857, 301-594-5400, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0373.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the *Federal Register* of February 9, 2000 (65 FR 6377), FDA announced the availability of a draft version of this guidance for industry entitled "Special Protocol Assessment." The agency has finalized that draft guidance after considering comments received on the draft guidance version. Eight comments were received, and minor changes were made to the draft guidance version in an effort to make the document more clear.

Section 119(a) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105-115) amends section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and directs FDA to allow sponsors to request special protocol assessment and for the agency to act on such requests. Moreover, in conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 in November 1997, FDA agreed to specific performance goals for special protocol assessment and agreement. The performance goals are summarized in an enclosure to a letter dated November 12, 1997, from the then Secretary of Health and Human Services, Donna E. Shalala, to Senator James E. Jeffords.

The procedures and policies described in this guidance were adopted by CDER and CBER for evaluating issues related to the adequacy (e.g., design, conduct, analysis) of proposed studies. These procedures will implement section 119(a) of the Modernization Act and are consistent with the timeframes described in the performance goals.

In the *Federal Register* document (65 FR 6377) announcing the availability of the draft version of this guidance, FDA published the proposed collection of information related to the draft guidance. The document also requested comments on the burden estimates for the draft guidance. In the *Federal Register* of May 29, 2001 (66 FR 29147), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance have been approved under OMB control number 0910-0470. This approval expires July 31, 2004. 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.

This level 1 guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). The guidance represents the agency's current thinking on special protocol assessment in CDER and CBER. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. The guidance will be updated as appropriate.

##### II. Comments

Interested persons may submit to the Dockets Management Branch (*see ADDRESSES*) written or electronic comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

##### III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder.guidance/index.htm>, or <http://www.fda.gov/cber/guidelines.htm>.

Dated: May 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-12327 Filed 5-16-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98D-0388]

#### Draft Guidance for Industry on Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance for industry entitled "Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release, and

Associated Studies." After careful consideration of the comments from the public and public advisory committees, FDA has decided to withdraw the draft guidance.

**FOR FURTHER INFORMATION CONTACT:** Dale P. Conner, Center for Drug Evaluation and Research (HFD-650), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5847.

**SUPPLEMENTARY INFORMATION:** In a notice published in the *Federal Register* of June 18, 1998 (63 FR 33375), FDA announced the availability of a draft guidance for industry entitled "Topical Dermatological Drug Product NDAs and ANDAs—In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies." The draft guidance was intended to provide recommendations to sponsors of new drug applications (NDAs), abbreviated new drug applications (ANDAs), and supplements on performing bioavailability and bioequivalence studies for topically applied dermatological drug products during either the preapproval or postapproval period. Written comments on the draft guidance were to be submitted by August 17, 1998. In the June 1998 notice, the agency also announced that it intended to discuss the guidance and the public response to the guidance before FDA public advisory committees. The draft guidance and public comments were discussed at joint meetings of the Advisory Committee for Pharmaceutical Science and the Dermatologic and Ophthalmic Drugs Advisory Committee on October 23, 1998, and November 17, 2000, and at a meeting of the Advisory Committee for Pharmaceutical Science on November 29, 2001.

The information and comments provided to FDA raised scientific concerns regarding the primary method, dermatopharmacokinetics (DPK), recommended in the draft guidance for documenting bioavailability and/or bioequivalence of topical dermatological drug products. The DPK method involves sampling of *stratum corneum* concentrations of drug over time after administration of a topical dermatological drug product. The information and comments from the public and advisory committees raised substantial doubt regarding: (1) The adequacy of the DPK method to assess the bioequivalence of topical dermatological drug products because the products are used to treat a variety of diseases in different parts of the skin, not just the *stratum corneum* and (2) the reproducibility of the DPK method between laboratories.

The agency plans to explore the development of new methods and improvements in current methods for documenting the bioequivalence of topical dermatological drug products.

Dated: May 6, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02-12326 Filed 5-16-02; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(6), as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Cancer Advisory Board.

**Dates:** June 11-12, 2002.

**Open:** June 11, 2002, 8:45 a.m. to 4 p.m.

**Agenda:** Program reports and presentations; Business of the Board.  
**Place:** National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

**Closed:** June 11, 2002, 4 p.m. to Recess.

**Agenda:** Review of grant applications; Discussion of confidential personnel issues.

**Place:** National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Bethesda, MD 20892.

**Open:** June 12, 2002, 8:45 a.m. to 10:50 a.m.

**Agenda:** Program reports and presentations; Business of the Board.

**Place:** National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

**Contact Person:** Dr. Marvin R. Kalt, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327. (301) 496-5147.

**Name of Committee:** National Cancer Advisory Board, Subcommittee on Cancer Centers.

**Time:** June 11, 2002, 12 p.m. to 1 p.m.

**Agenda:** To discuss activities related to the Subcommittee on Cancer Centers.

**Place:** National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

**Contact Person:** Dr. Brian Kimes, Executive Secretary, Subcommittee on Cancer Centers, National Cancer Institute, National Institutes of Health, 6116 Executive Blvd, Suite 700, Bethesda, MD 20892, (301) 496-8537.

Any interested person may file written comments with the committee by forwarding the statement of the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's Center home page: [deainfo.nci.nih.gov/advisory/ncab.htm](http://deainfo.nci.nih.gov/advisory/ncab.htm), where an agenda and any additional information for the meeting will be posted when available.

(Catalogus of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 13, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02-12454 Filed 5-16-