dated May 2003. On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (PDUFA III). Secretary Thompson's letter to Congress concerning PDUFA III included an addendum containing the performance goals and programs intended to facilitate the development and review of human drugs to which FDA had committed. One commitment was the establishment of a program that allows the sponsor of clinical trials for certain products to request that FDA engage an independent consultant to participate in the review of protocols for clinical studies that are intended to serve as the primary basis of claims of efficacy. This draft guidance document is intended to explain when and how a sponsor may take advantage of this program.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document. Two copies of mailed comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination 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 either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11214 Filed 5–6–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5453]

Guidance for Industry on Photosafety Testing; 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 ''Photosafety Testing.'' This guidance provides recommendations on when to test for photoirritation and assess the potential of drug products to enhance ultraviolet (UV)-associated skin carcinogenesis.

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

ADDRESSES: Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Abigail C. Jacobs, Center for Drug Evaluation and Research (HFD–540), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Photosafety Testing.'' This guidance provides recommendations on when to test for photoirritation and assess the potential of drug products to enhance UV-associated skin carcinogenesis.

In the **Federal Register** of January 10, 2000 (65 FR 1399), FDA published a notice making available a draft guidance entitled ''Photosafety Testing.'' The notice gave interested persons an opportunity to submit comments. As a result of the comments, certain sections of this guidance were reworded to improve clarity. This guidance further emphasizes that a flexible approach can be used to address adverse photoeffects and that a specific assay is not required. Moreover, it encourages the development of methods that can be efficiently used to evaluate human safety. This guidance describes a consistent, science-based approach for testing of topically and systemically administered drug products. It also describes basic concepts of photobiology and phototesting.

This guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115). The guidance represents the agency's current thinking on nonclinical photosafety testing. 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.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination 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/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: April 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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