

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

PMB

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[Docket No. 99D-5435]

Draft Guidance for Industry on Photosafety Testing; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Photosafety Testing." The draft guidance is intended to help applicants decide whether they should test for photosensitivity and assess potential human risk for photochemical carcinogenesis (cancer) and enhancement of UV-induced skin carcinogenesis during the development of topically and systemically administered drug products. The draft guidance describes a consistent, science-based approach for considering testing. FDA is soliciting comments and seeking information from interested persons concerning photosafety testing.

DATES: Submit written comments on the draft guidance document by *[insert date 90 days after date of publication in the **Federal Register**]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD-024), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5476.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled “Photosafety Testing.” This draft guidance is intended to help applicants decide whether to test for photosensitivity and potential human risk for photochemical carcinogenesis and enhancement of UV-induced skin carcinogenesis by topically and systemically administered drug products.

In the absence of data from photosensitivity tests conducted in animals or humans, warnings about the potential for photosensitization generally have been added to labels after adverse reactions resulted during widespread clinical use of products. Identification of photosensitivity effects before widespread human exposure is preferable to learning via adverse event reports.

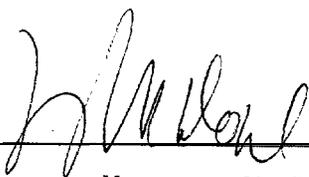
This draft guidance considers: (1) Photosensitivity and photocarcinogenicity, (2) testing of drug product or testing of drug substance, (3) testing for photosensitivity (photoirritation and photoallergy), (4) testing for the enhancement of UV-associated skin carcinogenesis (direct photochemical carcinogenicity or indirect effects in skin), (5) reasons for a separate approach to testing nonphotosensitizing drugs for long-term photosafety, and (6) current needs for assay development.

This Level 1 draft guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency’s current thinking on testing for photosafety. 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, regulations, or both.

Interested persons may, on or before *[insert date 90 days after date of publication in the Federal Register]*, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals

may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft 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.

Dated: 12/29/99
December 29, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

JP [FR Doc. ⁰⁰~~99~~-???? Filed ??-??-⁰⁰~~99~~; 8:45 am]

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