

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 99D-0236]

Draft Guidance for Industry on Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products.” This draft guidance provides assistance to sponsors of abbreviated new drug applications (ANDA’s) by recommending study designs and scoring systems that can be used to test skin irritation and sensitization during development of transdermal products. To fully evaluate the equivalence of a transdermal product to a reference listed drug, skin irritation and sensitization should be assessed because skin conditions may affect the efficacy or safety of the product. This guidance does not address the actual bioequivalence studies that would be needed for a particular transdermal drug product.

DATES: Written comments may be submitted on the draft guidance document by (*insert date 60 days after date of publication in Federal Register*).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ADDRESSES: Copies of this draft guidance for industry are available on the Internet at “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 Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary Fanning, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5845.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled “Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products.” Transdermal products have properties that may lead to skin irritation and/or sensitization. The delivery system, or the system in conjunction with the drug substance, may cause these skin reactions. In the development of transdermal products, dermatologic adverse events are evaluated primarily with animal studies and safety evaluations in the context of large clinical trials generally associated with the submission of new drug applications. Separate skin irritation and skin sensitization studies also are used for this purpose. These later studies are designed to detect irritation and sensitization under conditions of maximal stress. These studies may be used during the assessment of transdermal drug products for ANDA’s.

This draft level 1 guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). It represents the agency’s current thinking on skin irritation and sensitization testing of generic transdermal drug products. 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 statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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: February 19, 1999
February 19, 1999



William K. Hubbard
Associate Commissioner for Policy Coordination

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