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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0236]

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 guidance for industry entitled "Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products." This 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. Skin irritation and sensitization should be assessed because the condition of the skin may affect the absorption of a drug from a transdermal system, thus affecting the efficacy or safety of the product. This guidance does not address the actual bioequivalence studies necessary for a particular transdermal product.

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

ADDRESSES: Copies of this 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 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 guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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FOR FURTHER INFORMATION CONTACT: Mary M. 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 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 reactions. Skin irritation and skin sensitization studies are designed to detect irritation and sensitization under conditions of maximal stress and may be used during the assessment of transdermal drug product for ANDA’s.

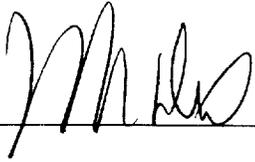
A draft guidance entitled “Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products” was published in the **Federal Register** of February 26, 1999 (64 FR 9516). Eight comments were received between February and April of 1999, and this guidance has been revised after careful consideration of those comments.

This Level 1 guidance is being issued consistent with FDA’s good guidance practices (62 FR 8961, February 27, 1997). The guidance 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 statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the 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 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: 1-24-00
January 24, 2000



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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