designation is requested (21 CFR 316.23). Copies of the orphan drug regulations (21 CFR part 316) (57 FR 62076, December 29, 1992) and explanatory background materials for use in preparing an application for orphan designation may be obtained from OPD (address above).

The names of the drugs and biologicals shown in the cumulative list of orphan designations may change upon marketing approval/licensing, reflecting the established, proper name approved by FDA. Because drugs and biologicals not approved/licensed for marketing are investigational, the appropriate established, proper name has not necessarily been assigned.

Dated: February 19, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–4764 Filed 2–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0349]

Guidance for Industry on SUPAC–IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum; 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 ''SUPAC–IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum.'' This guidance is intended to provide insight and recommendations to pharmaceutical sponsors of new drug applications and abbreviated new drug applications who wish to change equipment during the postapproval period.

DATES: Written comments may be submitted 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 ''SUPAC–IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), 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.

FOR FURTHER INFORMATION CONTACT: John L. Smith, Center for Drug Evaluation and Research (HFD–590), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2175.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''SUPAC–IR/MR: Immediate Release and Modified Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum.'' This guidance is intended to provide recommendations to pharmaceutical manufacturers using CDER's Guidance for Industry on ''Immediate Release Solid Oral Dosage Forms, Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation'' (SUPAC–IR), which published in November 1995 and CDER's Guidance for Industry ''SUPAC–MR: Modified Release Solid Oral Dosage Forms Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation,'' which published in September 1997.

This guidance is a revision of and supersedes the guidance entitled ''SUPAC–IR: Immediate Release Solid Oral Dosage Forms, Manufacturing Equipment Addendum,'' which published in October 1997. The guidance includes information on equipment used to manufacture modified release solid oral dosage form products as well as immediate release solid oral dosage form products and may be used to determine what documentation should be submitted to FDA regarding equipment changes made in accordance with the recommendations in the SUPAC–IR guidance and SUPAC–MR guidance.

This guidance represents the agency's current thinking on scale-up and postapproval equipment changes for immediate release and modified release solid oral dosage forms regulated by CDER. 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 statute, 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: February 19, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–4767 Filed 2–25–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 April 27, 1999. 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.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Persistent Effect of Treatment in Cuyahoga County, Ohio—New—The Center for Substance Abuse Treatment (CSAT) is undertaking a major initiative to study the long-term course of substance abuse within the context of receipt of substance abuse treatment. It has often been observed that success in treating substance abuse may require multiple episodes of treatment. The Persistent Effects of Treatment Studies (PETS) will be a family of studies structured to provide data on a wide range of populations and treatment approaches over a three-year period following admission to a substance abuse treatment program in a community setting. The family of studies will be built on existing studies currently being conducted by other organizations (including Federal, State, and local governments) in order to minimize costs and response burden. Collectively, the PETS studies are expected to provide valuable insights into the factors that lead to long-term success in treatment of substance abuse.

Persistent Effects of Treatment in Cuyahoga County, Ohio, is the first of these studies. Under the aegis of an existing, CSAT-funded, Target Cities cooperative agreement, the county has built a strong substance abuse treatment information capability including standardized client intake assessment using the computerized Central Intake Assessment Instrument (CIAI–C), sound and comprehensive treatment information systems, and ongoing client follow-up at 6- and 12-months after treatment. This proposed project will build upon this foundation by conducting additional interviews at 24, 30, and 36 months after treatment admission using the computerized CIAI–C Followup version. At month 36, additional information needed to construct a natural history of substance use, treatment, criminal justice involvement, and employment for each subject over the previous 4-year period will be collected.

The estimated response burden over the three-year period of approval is summarized below.

	Number of respondents	Number of responses/ respondent	Average burden/ response (hours)	Total burden (hours)
CIAI–C Followup Interview	1,297	3	1.5	5,837
Natural History Interview	1,038	1	1.0	1,038
Total				6,875