DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0371]

Agency Information Collection Activities; Announcement of OMB Approval; Prescription Drug Product Labeling, Medication Guide Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Prescription Drug Product Labeling, Medication Guide Requirements'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 1, 1998 (63 FR 66378), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0393. The approval expires on January 31, 2002.

Dated: February 19, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–4765 Filed 2–25–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0165]

Agency Information Collection Activities; Announcement of OMB Approval; Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Regulations Requiring Manufacturers to Asses the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 15, 1997 (62 FR 43903), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0392. The approval expires on January 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: February 19, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–4766 Filed 2–25–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the cumulative list of orphan drug and biological designations as of December 31, 1998. FDA has announced the availability of previous lists, which are updated monthly, identifying the drugs and biologicals granted orphan designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the cumulative list of orphan drug and biological designations are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Lisa M. Hubbard or Stephanie Donahoe, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan designation of their drug or biological under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act which requires public notification of designations, FDA maintains a cumulative list of orphan drug and biological designations. This list includes the name of the drug or biological, the specific disease/condition for which the drug or biological is designated, and information about the sponsor such as the name, address, telephone number, and contact.

At the end of each calendar year, the agency publishes a cumulative list of orphan drug and biological designations current through the calendar year. The list that is the subject of this notice is the cumulative list of orphan drug and biological designations through December 31, 1998, and, therefore, brings the January 30, 1998 (63 FR 4644), publication up to date. This list is available upon request from the Dockets Management Branch (address above). Those requesting a copy should specify Docket No. 84N–0102, which is the docket number for this notice. In addition, the list is updated monthly and is available upon request from OPD or FDA's Dockets Management Branch (address above). The current list is also available on the website, http://www.fda.gov/orphan.

The orphan designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing a drug or biological for an orphan indication must apply for orphan designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which

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]

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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/