DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0488]

Agency Information Collection Activities; 1998 and Year 2000 Update of a National Survey of Prescription Drug Information Provided to Patients; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''1998 and Year 2000 Updates of a National Survey of Prescription Drug Information Provided to Patients'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

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 Thursday, December 11, 1997 (62 FR 65273), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection and has assigned OMB control number 0910–0279. The approval expires on May 31, 1999.

Dated: August 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23028 Filed 8–26–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0693]

Draft ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test.'' The draft guidance document, when finalized, is intended to provide guidance to applicants who wish to market an allergenic product or allergen patch test for the completion of the chemistry, manufacturing and controls (CMC) section and the establishment description section of revised Form FDA 356h entitled ''Application to Market a New Drug, Biologic, or an Antibiotic for Human Use.'' This draft guidance document is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the Food and Drug Administration Modernization Act of 1997, and is intended to reduce unnecessary burdens on industry without diminishing public health protection.

DATES: Written comments may be provided at any time, however, comments should be submitted by October 26, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: On the Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for an Allergenic Extract or Allergen Patch Test.'' The draft guidance document, when finalized, is intended to provide manufacturers of allergenic products and allergen patch tests guidance on the kinds of information that should be gathered to adequately describe steps of manufacturing, product validation, final container filling, and other aspects of production. The draft also provides guidance on how the information should be formatted and organized when submitted with Form FDA 356h entitled ''Application to Market a New Drug, Biologic, or an Antibiotic for Human Use.''

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a new harmonized Form FDA 356h entitled ''Application to Market a New Drug, Biologic, or an Antibiotic for Human Use.'' The new harmonized form is intended to be used by applicants for all drug and biological products. The new harmonized form, when fully implemented, will allow biological product manufacturers to submit a single application, the biologics license application, instead of two separate license application submissions (product license application and establishment license application).

This draft guidance document represents the agency's current thinking with regard to the content and format of the CMC and establishment description sections of an application to market an

allergenic extract or allergen patch test. 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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by October 26, 1998, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: August 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23024 Filed 8–26–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0307]

Draft Guidance for Industry; Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to November 24, 1998, the comment period for the draft guidance document that appeared in the **Federal Register** of June 12, 1998 (63 FR 32219). The draft guidance document addressed issues concerning the exportation of human drugs, animal drugs, biologics, food additives, and devices under the FDA Export Reform and Enhancement Act, as well as the importation of components, parts, accessories, or other articles for incorporation or further processing into articles intended for export. This action is being taken in response to a request from the Health Industry Manufacturers Association.

DATES: Written comments by November 24, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 12, 1998 (63 FR 32219), FDA published a draft guidance document entitled ''FDA Draft Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996.''

Enacted and later amended in 1996, the FDA Export Reform and Enhancement Act (Pub. L. 104–134, as amended by Pub. L. 104–180) significantly changed the export requirements for human drugs, animal drugs, biologics, devices, and, to a limited extent, food additives. For example, before the law was enacted, most exports of unapproved new drug products could only be made to 21 countries identified in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382), and these exports were subject to various restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA). (Currently, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA.)

The draft guidance document provides information on the statutory requirements for exporting human drugs, animal drugs, biologics, and medical devices; general requirements for products exported under section 801 of the act (21 U.S.C. 381); labeling requirements for drugs and biologics exported under section 801(e) of the act; requirements for exports of unapproved drugs, biologics, and devices under section 802(b) of the act; requirements for exports of unapproved drugs and devices for investigational use; requirements for exports of unapproved drugs and devices in anticipation of foreign approval; requirements for exports of drugs and devices for diagnosing, preventing, or treating a tropical disease or a disease ''not of significant prevalence in the United States;'' export notifications to FDA; and ''import for export.''

The draft guidance document represents the agency's current thinking on exports and imports-for-export under sections 801 and 802 of the act. 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.

On June 23, 1998, the Health Industry Manufacturers Association (HIMA) requested a 90-day extension of the comment period. HIMA explained that ''the complexity of the issues with the additional complication of summer vacation schedules prevents us from providing substantive comments within the time provided.'' The agency considered HIMA's request and, through this notice, is extending the comment period by 90 days until November 24, 1998.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document. 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. A copy of the draft guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. The draft