effective. However, FDA records indicate that the IND effective date was September 3, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 8, 1998. FDA has verified the applicant's claim that the new drug application (NDA) for Definity (NDA 21–064) was initially submitted on December 8, 1998.

3. *The date the application was approved*: July 31, 2001. FDA has verified the applicant's claim that NDA 21–064 was approved on July 31, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,418 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by September 24, 2002. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 22, 2003. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit a single copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 22, 2002.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 02–18975 Filed 7–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0254]

Draft Guidance for Industry on Inhalation Drug Products Packaged in Semipermeable Container Closure Systems; Availability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 ''Inhalation Drug Products Packaged in Semipermeable Container Closure Systems.'' This draft guidance is intended to provide guidance for industry on inhalation drug products that are packaged in semipermeable primary container closure systems. This draft guidance also covers related chemistry, manufacturing, and controls (CMC) considerations. FDA is issuing this draft guidance to address public health concerns raised by the possible leaching and entry of chemical contaminants into inhalation drug products packaged in semipermeable primary container closure systems.

DATES: Submit written or electronic comments on the draft guidance by October 24, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), 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 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Badrul Chowdhury or Guirag Poochikian, Center for Drug Evaluation and Research (HFD–570), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Inhalation Drug Products Packaged in Semipermeable Container Closure Systems.'' Inhalation drug products used in the treatment of patients with asthma or chronic obstructive pulmonary disease may be packaged in semipermeable primary container closure systems, such as low-density polyethylene. Over time, chemical impurities can accumulate in an inhalation drug product packaged in semipermeable primary container closure systems as a result of the degradation of formulation components, leaching from the container closure system, and/or entry from the local environment. Volatile chemical components from the local environment, including the secondary packaging, can react with the drug product formulation to form different impurities. The clinical consequences of chemical contamination of inhalation drug products are uncertain; however, given the known sensitivity of patients using these products to respiratory irritants and sensitizers, it is possible that these chemical contaminates may induce bronchospasm. Because bronchospasm is also the indication for which the inhalation drug product is used, it is difficult in the clinical setting to establish whether bronchospasm after the use of a drug product may be due to chemical contaminants or to a patient's underlying disease. Since it is possible that chemical contaminants in the inhalation drug products used to treat critically ill patients could adversely affect such patients, FDA is issuing this draft guidance to provide recommendations for inhalation drug products packaged in semipermeable primary container closure systems. This draft guidance provides recommendations on: (1) Appropriate protective secondary packaging, (2) embossing and/or debossing of the primary container in lieu of paper labels, and (3) general guidance on the number of unit-dose containers to be contained within each protective secondary package. These recommendations apply to drug products, both those in development and those already approved and marketed in the United States.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on inhalation drug products packaged in semipermeable container closure systems. 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 and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–19020 Filed 7–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing the continuation of the Regulatory Project Manager Site Tours. This training program, initiated in 1999, gives CDER's regulatory project managers an opportunity to tour pharmaceutical facilities. The program provides regulatory project managers and their industry counterparts an opportunity to share their regulatory experiences. The program is intended to enhance review efficiency and quality by providing CDER staff with a better understanding of the pharmaceutical industry and its operation, and to improve communication and cooperation between CDER staff and industry. The purpose of this notice is to invite pharmaceutical companies interested in participating in these programs to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas by September 9, 2002.

FOR FURTHER INFORMATION CONTACT: Sean J. Belouin, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2481, FAX 301–827–2523, e-mail: BELOUINS@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing the Regulatory Project Manager Site Tours to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide: (1) Firsthand exposure to industry's drug development processes, and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. Regulatory Project Manager Site Tours and Regulatory Interactions

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, may observe operations of pharmaceutical manufacturing, packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. The purpose of this tour, or any part of the program, is meant to improve mutual understanding and to provide an avenue for open dialogue.

During the site tours, regulatory project managers and their industry counterparts will also participate in daily workshops focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management team techniques and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER, therefore, selection of potential facilities will be based on available resources for this program.

If your firm is interested in offering a site tour or learning more about this training opportunity, please submit a proposed agenda to Sean J. Belouin (see **FOR FURTHER INFORMATION CONTACT**).

Dated: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–19019 Filed 7–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Regulations and Forms (OMB No. 0915–0126)—Revision

The National Practitioner Data Bank (NPDB) was established through Title IV of Pub. L. 99–660, the Health Care Quality Improvement Act of 1986, as amended. Final regulations governing the NPDB are codified at 45 CFR part 60. Responsibility for NPDB