review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Denavir™ (Penciclovir). Denavir™ is indicated for the treatment of recurrent herpes labialis (cold sores) in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Denavir™ (U.S. Patent No. 5,075,445) from Beecham Group p.l.c., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 28, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Denavir™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Denavir™ is 1,299 days. Of this time, 954 days occurred during the testing phase of the regulatory review period, 345 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: March 7, 1993. The applicant claims March 5, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 7, 1993, 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 of the act*: October 16, 1995. FDA has verified the applicant's claim that the new drug application (NDA) for Denavir™ (NDA 20–629) was initially submitted on October 16, 1995.

3. *The date the application was approved*: September 24, 1996. FDA has verified the applicant's claim that NDA 20–629 was approved on September 24, 1996.

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 640 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 9, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 8, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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 (address above) in three copies (except that individuals may submit single copies) and 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 29, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–11585 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Airline Catering Workshop on Sanitation, HACCP and the 1999 Food Code; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA), in cooperation with the International Inflight Food Service Association, is announcing the following workshop: Airline Catering Workshop on Sanitation, HACCP and the 1999 Food Code. The workshop will discuss issues on sanitation, Hazard Analysis Critical Control Point and the 1999 Food Code.

Date and Time: The workshop will be held on Wednesday, June 2, 1999, 8:30 a.m. to 5 p.m.

Location: The workshop will be held at the Marriott Hotel, 1500 Convention Center Dr., Arlington, TX 76011, 817–261–8200.

Contact: Martha S. Baldwin, Dallas District, Food and Drug Administration, 3310 Live Oak St., Dallas, TX 75204, 214–655–5310, ext. 544, FAX 214–655–5200, e-mail ''mbaldwin@ora.fda.gov''.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by May 26, 1999.

If you need special accommodations due to a disability, please contact Martha S. Baldwin at least 7 days in advance.

Dated: May 4, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–11736 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0228]

Guidance for Industry: Computerized Systems Used in Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled

''Guidance for Industry: Computerized Systems Used in Clinical Trials.'' The guidance document provides guidance for computerized systems used to create, modify, maintain, archive, retrieve, or transmit clinical data intended for submission to FDA. Whether collected or reported electronically or in paper form, clinical data must meet certain quality standards, and this guidance is intended to provide information on how computerized systems can meet these standards.

DATES: Written comments on the guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials'' to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs (ORA), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0425.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials.'' This guidance pertains to long-standing regulations covering clinical trial records under 21 CFR parts 300, 500, and 800. On March 20, 1997 (62 FR 13430), FDA published a regulation providing uniform, enforceable, baseline standards for electronic records and electronic signatures, codified in 21 CFR part 11. To formulate supplemental guidance on the use of computerized systems in clinical trials, an agency working group representing the Bioresearch Monitoring Program Managers from each center within FDA and the Office of Regulatory Affairs prepared a draft of this present guidance. In the **Federal Register** of June 18, 1997 (63 FR 33094), FDA published the draft guidance which allowed 60 days for public comment. Upon petition, FDA extended the comment period for an additional 60 days. FDA received more than 500 comments from 24 respondents. Over the following 12 months, the agency working group reviewed all public comments and made appropriate changes to the guidance.

This guidance document represents the agency's current thinking on computerized systems used in clinical trials. 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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information contained in the guidance document may be applicable to all situations. The document is intended to provide useful information and does not set forth requirements.

II. Comments

Interested persons, may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of 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.

III. Electronic Access

Persons with access to the Internet may obtain the guidance using the World Wide Web (WWW). For WWW access, connect to the Office of Regulatory Affairs at ''http://www.fda.gov/ora/compliance__ref/bimo/default.html''.

Dated: May 3, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–11582 Filed 5–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0512]

''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h, 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use;''' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h, 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use.''' This guidance document is intended to assist applicants in the preparation of the content and format of the chemistry, manufacturing, and controls (CMC) section and the establishment description section of a biologics license application (BLA), revised Form FDA 356h, for human blood and blood components intended for transfusion or for further manufacture. In addition, this guidance document provides assistance for the completion of the BLA. This action 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 (Modernization Act), to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and For the Completion of the Form FDA 356h,