Dated: April 8, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–9225 Filed 4–14–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0368]

Draft Guidance for Industry on Submitting Marketing Applications According to the ICH/CTD Format; General Considerations; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 16, 2003, the comment period for the draft guidance for industry entitled ''Submitting Marketing Applications According to the ICH/CTD Format; General Considerations'' that appeared in the **Federal Register** of September 5, 2001 (66 FR 46464). The agency is taking this action in response to several informal requests for an extension of the comment period.

DATES: Submit written or electronic comments on the draft guidance by June 16, 2003. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20857, 301–594–5400; or Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 5, 2001 (66 FR 46464), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Submitting Marketing Applications According to the ICH/CTD Format; General Considerations.'' This guidance provides information on how to organize new drug applications, abbreviated new drug applications, and biologics license applications based on the International Conference on Harmonization M4 guidance on organizing the Common Technical Document for the registration of pharmaceuticals for human use. Interested persons were given until November 5, 2001, to submit written or electronic comments on the draft guidance. In response to several informal requests from drug and biologic manufacturers, FDA has decided to reopen the comment period on the draft guidance until June 16, 2003, to allow interested persons additional time to submit comments.

II. Comments

Interested persons may, on or before June 16, 2003, submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, 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 draft guidance document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: April 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9224 Filed 4–14–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: March 2003

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of March 2003, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
AIRD, EILEEN B ..... RIDGEWOOD, NJ	04/20/2003
ALMAZAN, MARIA ..... LA CANADA, CA	04/20/2003
AMADOR, CARLOS ..... MIAMI, FL	04/20/2003
AMY, LESLIE W ..... RAYBROOK, NY	04/20/2003
BAIRD, KARIN LYNN ..... YUCAIPA, CA	04/20/2003
BARON, ADOLFO ..... MIAMI, FL	04/20/2003
BENTHALL, MARK JOSEPH ... ST LOUIS, MO	04/20/2003
BOOKER, THELMA A ..... ATCHISON, KS	04/20/2003
BREARY, CHESTER H JR ..... ORIENT, OH	04/20/2003
BRINGAS, AL ..... YAZOO CITY, MS	04/20/2003
CANABAL-ENRIQUEZ, JOSE .. YAUCO, PR	04/20/2003
CANET, FRANCISCO	04/20/2003