§ 71.1 [Corrected]

On page 23623, Column 3, second paragraph from the bottom, change ''North Central Missouri Regional Airport, MO'' to read ''Brookfield, North Central Missouri Regional Airport, MO.''

Issued in Kansas City, MO, on May 8, 2003.

David W. Hope,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 03–12378 Filed 5–16–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 111 and 112

[Docket No. 96N–0417]

RIN 0910–AB88

Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to August 11, 2003, the comment period for a proposed rule published in the **Federal Register** of March 13, 2003. The proposed rule would establish the minimum current good manufacturing practices (CGMPs) necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. This action is being taken in response to requests for more time to submit comments to FDA.

DATES: Submit written or electronic comments on the proposed rule by August 11, 2003.

ADDRESSES: Submit written comments 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*.

FOR FURTHER INFORMATION CONTACT: Karen Strauss, Center for Food Safety and Applied Nutrition (HFS–821), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 02740–3835, 301–436–2375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 13, 2003 (68 FR 12158), FDA published a proposed rule that, if finalized, would establish the minimum CGMPs necessary to ensure that, if you engage in activities related to manufacturing, packaging, or holding dietary ingredients or dietary supplements, you do so in a manner that will not adulterate and misbrand such dietary ingredients or dietary supplements. The proposed provisions would require manufacturers to evaluate the identity, purity, quality, strength, and composition of the dietary ingredients and dietary supplements.

In the March 13, 2003, proposed rule, FDA announced that the time period for public comment would be 90 days from the date of the publication in the **Federal Register**. On April 21, 2003, FDA received a request to allow an additional 60 days for interested persons to comment. In addition, on April 25, 2003, FDA received a request to allow an additional 90 days for interested persons to comment. The requesters assert that the time period of 90 days is insufficient to respond fully to FDA's multiple requests for comments and analyses and to enable all potential respondents adequate time to conduct the research necessary to provide complete scientific responses to questions posed in the proposed rule.

FDA believes that an extension of the comment period is appropriate, given the variety of issues raised by the proposed rule. However, because the agency wants to move forward on finalizing the rule as quickly as possible, FDA is extending the comment period only for an additional 60 days, until August 11, 2003. This extension will provide the public with a total of 150 days to submit comments. FDA does not intend to grant any additional time for extensions of the comment period.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the proposal. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 10, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12366 Filed 5–16–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98D–0785]

Draft Guidances for Industry on Medical Imaging Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three draft guidances for industry on ''Developing Medical Imaging Drug and Biological Products.'' These draft guidances are intended to assist developers of medical imaging drug and biological products (medical imaging agents) in planning and coordinating their clinical investigations and preparing and submitting investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), abbreviated new drug applications (ANDAs), and supplements to NDAs or BLAs. The draft guidances provide information on how FDA will interpret and apply certain provisions in the agency's regulations on in vivo radiopharmaceuticals used for diagnosis and monitoring of diseases and conditions.

DATES: Submit written or electronic comments on the draft guidances by June 18, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidances 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 Communications, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist either office in processing your request. Submit written comments on the draft guidances 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 guidances.

FOR FURTHER INFORMATION CONTACT: Kyong Kang, Center for Drug Evaluation and Research (HFD–160), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7510, or George Q. Mills, Center for Biologics Evaluation and Research (HFM–573), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–5097.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 14, 1998 (63 FR 55067), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Developing Medical Imaging Drugs and Biologics'' (the medical imaging draft guidance). In a document published in the **Federal Register** of January 5, 1999 (64 FR 457), FDA reopened the comment period on the medical imaging draft guidance until February 12, 1999. In a document published in the **Federal Register** of February 16, 1999 (64 FR 7561), FDA extended the comment period until April 14, 1999.

FDA received numerous written comments on the medical imaging draft guidance. In addition, the agency held public meetings on January 25 and March 26, 1999, to discuss various issues concerning the medical imaging draft guidance. In the **Federal Register** of July 31, 2000 (65 FR 46674), the agency published a notice announcing the availability of a revised draft guidance.

After considering the comments that FDA received on the revised draft guidance, the agency has decided to issue the guidance again as a draft for comment. The agency has divided the draft guidance into three parts to make it more user-friendly. These three draft guidances are intended to assist developers of medical imaging agents in planning and coordinating their clinical investigations and preparing and submitting INDs, NDAs, BLAs, ANDAs, and supplements to NDAs or BLAs.

Part 1 of ''Medical Imaging Drug and Biological Products,'' entitled ''Conducting Safety Assessments,'' discusses how to conduct safety assessments of medical imaging agents. Part 2, entitled ''Clinical Indications,'' discusses how clinical development programs for medical imaging agents can be tailored to reflect the use of these agents for diagnosis and monitoring of diseases and conditions. Part 3, entitled ''Design, Analysis, and Interpretation of Clinical Studies,'' discusses how to design a clinical development program for a medical imaging agent, including selecting subjects, and how to acquire, analyze, and interpret medical imaging data. Collectively, once finalized these draft guidances will provide information on how FDA will interpret and apply certain provisions in the final rule, published in the **Federal Register** of May 17, 1999 (64 FR 26657), on the evaluation and approval of in vivo radiopharmaceuticals used in diagnosis and monitoring.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the agency's current thinking on different aspects of the development of medical imaging agents. They do not create or confer any rights for or on any person and do 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 guidances. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidances and received comments may be seen 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 documents at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

IV. The Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The guidances would not impose any additional reporting burden because information on the safety and effectiveness of medical imaging agents in applications for marketing approval and INDs is already required by existing regulations. In fact, clarification by the guidances of FDA's standards for evaluation of medical imaging agents is expected to reduce the overall burden of information collection. FDA received no comments on the analysis of information collection burdens stated in the notice of availability of the original draft guidance published in the **Federal Register** on October 14, 1998 (63 FR 55067). In the **Federal Register** of July 31, 2000 (65 FR 46674), the agency requested comments on the revised proposed collections of information. No comments were received.

Dated: May 10, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–12370 Filed 5–16–03; 8:45 am]

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