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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 111

[Docket No. 2007N-0186]

RIN 0910-AB88

Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to October 24, 2007, the comment period for the interim final rule (IFR) that appeared in the Federal Register of June 25, 2007 (72 FR 34959). In the IFR, FDA requested comments on a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. The agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: Submit written and electronic comments by October 24, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2007N-0186, and/or Regulation Identifier Number (RIN) 0910-AB88, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

Federal eRulemaking Portal: <http://www.regulations.gov>.

Follow the instructions for submitting comments.

Agency Web site: <http://www.fda.gov/dockets/ecomments>.

Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

FAX: 301-827-6870.

Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously in the ADDRESSES portion of this document under Electronic Submissions.

Instructions: All submissions received must include the agency name and Docket No(s). and/or RIN for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For

additional information on submitting comments, see the ``Comments'' heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm>

and insert the docket number(s), found in brackets in the heading of this document, into the ``Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vasilios Frankos, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1696.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 25, 2007 (72 FR 34959), FDA published an IFR with a 90-day comment period to request comments on a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. Comments on the exemption procedure will provide an opportunity for interested persons to comment on whether this exemption procedure should be modified, and if so, whether there is any additional information that may be helpful to articulate with respect to what a petition needs to show that may inform future guidance.

The agency has received a request for a 60-day extension of the comment period for the IFR. The request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the IFR.

FDA has considered the request and is extending the comment period for the IFR for 30 days, until October 24, 2007. The agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments on this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 11, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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