

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 192 and 592

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[Docket No. 00N-1396]

RIN 0910-AC15

Premarket Notice Concerning Bioengineered Foods; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to May 3, 2001, the comment period for a proposed rule published in the **Federal Register** of January 18, 2001. The proposed rule would require the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. This action is being taken in response to a request for more time to submit comments to FDA.

DATES: Submit written comments on the proposed rule by May 3, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or via e-mail to FDADockets@oc.fda.gov. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding human food issues: Linda S. Kahl, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3101.

Regarding animal feed issues: William D. Price, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6652.

SUPPLEMENTARY INFORMATION:**I. Extension of Comment Period**

In the **Federal Register** of January 18, 2001 (66 FR 4706), FDA published a proposed rule that, if finalized, would require the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals. FDA proposed that this submission be made at least 120 days prior to the commercial distribution of such foods. FDA took this action to ensure that it would have the appropriate amount of information about bioengineered foods to help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the law. The proposed action would permit the agency to assess on an ongoing basis whether plant-derived bioengineered foods comply with the standards of the Federal Food, Drug, and Cosmetic Act.

In the January 18, 2001, proposed rule, FDA announced that the timeframe for public comments would be 75 days from the date of publication in the **Federal Register**. On March 15, 2001, FDA received a request to allow an additional 60 days for interested persons to comment. In the requester's view, the time period of 75 days was insufficient to prepare thoughtful and responsive comments in light of the variety of difficult legal, procedural, and scientific issues raised by the proposed rule.

FDA believes that an extension of the comment period is appropriate given the variety of legal, procedural, and scientific issues raised by the proposed rule. However, FDA does not agree that an additional 60 days is warranted, because FDA announced its intent to conduct this rulemaking more than 8 months prior to publication of the proposed rule (Ref. 1). Therefore, FDA is extending the comment period for an additional 30 days, until May 3, 2001. This extension will provide the public with a total of 105 days to submit comments.

II. How to Submit Comments

You may submit to the Dockets Management Branch (address above) written comments regarding the proposed rule by May 3, 2001. You must submit two copies of any comments, except that if you are an individual you may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. You may view received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

You may also send comments to the Dockets Management Branch via e-mail to FDADockets@oc.fda.gov. You should annotate and organize your comments to identify the specific issues to which they refer.

III. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Press Release, U.S. Department of Health and Human Services, "FDA to Strengthen Pre-market Review of Bioengineered Foods," May 3, 2000, available at <http://vm.cfsan.fda.gov>.

Dated: March 27 2001
March 27, 2001.

Ann M. Witt

Ann M. Witt,
Acting Associate Commissioner for Policy.

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Wendie Oliver

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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