FDA ANNOUNCES PROPOSAL AND DRAFT GUIDANCE FOR FOOD DEVELOPED THROUGH BIOTECHNOLOGY

The Food and Drug Administration (FDA) today issued a proposed rule and a draft guidance document concerning food developed through biotechnology. The proposed rule, if finalized, would require food developers to notify FDA at least 120 days in advance of their intent to market a food or animal feed developed through biotechnology and to provide information to demonstrate that the product is as safe as its conventional counterpart. FDA is also proposing to increase the transparency of the agency's review process for such foods.

In a separate but related action, FDA is issuing a draft guidance document, which if finalized, would provide direction to manufacturers who wish to label their food products as being made with or without ingredients developed through biotechnology.

"These initiatives will further assure that all food products developed using the tools of modern biotechnology are known to the Food and Drug Administration, so that FDA can continue to examine these products before they reach the market" said Jane E. Henney, M.D., Commissioner of Food and Drugs. "These measures will permit the review process to be more transparent to the public, one of the primary issues voiced during FDA's public hearings on this issue."

Currently, developers of food and feed developed through biotechnology participate in a voluntary consultation program with FDA. To date, all such food and feed marketed in the U.S. have gone through the consultation program before they have entered the market.

Although this voluntary consultation process has worked well since its inception in 1994, a series of FDA-sponsored public meetings and subsequent written public comments indicated considerable public support for a mandatory and more transparent process. The proposed rule announced today, would, if finalized make mandatory pre-market consultation for bioengineered foods and feeds. In addition, consistent with applicable disclosure rules, FDA intends to post information submitted by manufacturers, as well as FDA's responses, in the agency's electronic reading room. This information can be reached through FDA's Website at www.fda.gov/foi/electrr.htm. This proposed rule can be accessed at www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm.
The draft guidance on labeling will assist manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients. This guidance will aid manufacturers in ensuring that their labeling is truthful and not misleading. The FDA views the terms "derived through biotechnology" and "bioengineered" as acceptable. Examples of terms that are not acceptable are "GM free", "GMO", and "modified."

Written comments on the proposed rule to require premarket notification may be submitted by March 28, 2001 to Dockets Management Branch (HFA-305), Food and Drug Administration 5630 Fishers Lane, Rm. 1061, Rockville MD 20852.

Written comments on the information collection provisions of the proposed rule may be submitted by February 12, 2001 to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 724 17th St. NW, rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

A copy of the draft guidance on labeling bioengineered foods is available on the Internet at www.cfsan.fda.gov/~dms/guidance.html. It may also be requested by calling 202-205-4561, faxing a request to 202-205-4594, or writing to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St., SW, Washington, D.C. 20204 (enclose a self addressed label or include a fax number with the request).

To ensure adequate consideration, written comments on the labeling guidance should be submitted by March 13, 2001. However, comments on the guidance may be submitted at any time. Written comments concerning the collection of information provisions of the draft labeling guidance may be submitted by March 13, 2001. All comments on the draft guidance may be submitted to the Dockets Management Branch at the address above.

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This is a mirror of the page at http://www.fda.gov/bbs/topics/NEWS/2001/NEW00747.html

Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering Draft Guidance for Industry, January 2001

Report on Consumer Focus Groups on Biotechnology and Labeling

This document was issued on January 17, 2001.

For more recent information on Food Labeling

See http://www.cfsan.fda.gov/label.html

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