City: _____

State: _____

Zip Code: _____

Phone: ( ) _____

FAX: ( ) _____

E-mail: _____

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The workshop is being held in response to a request by the State of Missouri to present information that would be helpful to regulated industry. The Small Business Program presents this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with labeling requirements, especially in light of growing concerns about food allergens. Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) FDA food regulations, (2) food labeling, (3) allergen declaration, (4) good manufacturing practices, and (5) the Nutrition Labeling Education Act. FDA expects that participation in this workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food labeling and allergen declaration.

Dated: December 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–31572 Filed 12–19–01; 12:37 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0465]

Guidance for Industry on Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications.'' This guidance is a second revision of the guidance entitled ''Major, Minor, FAX, and Telephone Amendments to Original Abbreviated New Drug Applications.'' FDA's Office of Generic Drugs (OGD) determined that further revision of the policy regarding determination of major, minor, and telephone amendments was necessary to help streamline the review of abbreviated new drug applications (ANDAs).

DATES: Submit written or electronic comments on the guidance by March 21, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Rita R. Hassall, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications.'' The guidance is intended to document OGDs policy regarding the determination of major, minor, and telephone amendments to original and supplemental ANDAs. This guidance first published in August 1999 and was originally entitled ''Major, Minor, FAX, and Telephone Amendments to Original Abbreviated New Drug Applications.'' It was revised in May 2000 to explain that the issuance of a major, minor, or FAX amendment would stop the review clock.

The second revision of this guidance (1) deletes the FAX amendment designation, which was found to be unnecessary, (2) now applies to supplemental applications as well, and (3) changes the criteria for determining the type of amendment. The changes in criteria should result in more amendments being categorized as ''minor'' and fewer as ''major.'' A minor amendment request (generally reviewed within 30 to 60 days) has a higher priority than a major amendment. Since the review of a minor amendment takes place sooner than a major amendment after the original review, there is not a long break in the review process for a minor amendment. The response to a major amendment request, however, goes into the 180-day queue. This process causes a greater time lapse from when the original review was done and results in reviewers having to refamiliarize themselves with the application. It is expected that the new policy will help in moving applications through the approval process more quickly than under the previous policy. Thus the total time for approval of ANDAs will be reduced.

Because it lessens the burden on industry, this guidance is being issued as a Level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115). As with other Level 1 guidances for immediate

implementation, the agency is soliciting comments from the public. This guidance represents the agency's current thinking on major, minor, and telephone amendments to ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comments are to be submitted, 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 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 document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: December 3, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–31454 Filed 12–20–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0493]

Draft Guidance for Industry: Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Reduction; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Reduction.'' This draft document is intended to provide guidance to fruit and vegetable juice producers about FDA's revised recommendations for effectively achieving a 5-log pathogen reduction that is the basis for exempting juice products from the warning label requirement established by a July 8, 1998, final rule entitled ''Food Labeling: Warning and Notice Statement; Labeling of Juice Products'' (the juice labeling rule). A 5-log reduction is also a requirement of the January 19, 2001, final rule entitled ''Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice'' (the juice HACCP rule). This draft guidance describes FDA's current recommendations for effectively achieving a 5-log pathogen reduction in juice.

DATES: Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance document by February 19, 2002. Comments on this guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Jennifer A. Burnham, Center for Food Safety and Applied Nutrition (CFSAN) (address below).

Submit written comments on the document 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: Jennifer A. Burnham, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–0773, FAX: 202–205–4422.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has revised its guidance for effectively achieving a 5-log pathogen reduction in juice. The purpose of this guidance is to encourage those juice processors not yet subject to the juice HACCP rule (e.g., small and very small processors who are not subject to the juice HACCP rule until January 21, 2003 and January 20, 2004, respectively) who are performing a 5-log reduction to attain exemption from the warning label requirement to apply effective 5-log reduction treatments based upon current science. This draft guidance also provides guidance to processors at retail who are not subject to the juice HACCP rule and who are performing a 5-log reduction to attain exemption from the warning label requirements.

In the **Federal Register** of July 8, 1998, FDA issued the juice labeling rule (63 FR 37030). That final rule requires a warning statement on fruit and vegetable juices and juice ingredients that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. Specifically, under 21 CFR 101.17(g), juice and juice ingredients must bear a warning label if they have not been processed to achieve a 5-log pathogen reduction, or a reduction that is equal to, or greater than, the criterion established for process controls by any final regulation requiring the application of HACCP principles to the processing of juice and juice ingredients. The warning label was intended to provide a measure of public safety until final HACCP regulations could be established and implemented.

In the **Federal Register** of January 19, 2001 (66 FR 6138), FDA issued the juice HACCP rule; this rule mandates the implementation of HACCP principles and an effective 5-log pathogen reduction treatment to ensure the safe and sanitary processing of fruit and vegetable juices and ingredients. In the juice HACCP rule, FDA set forth certain criteria for achieving the 5-log pathogen reduction, which are consistent with current scientific knowledge as described in the juice HACCP rule. This draft guidance will assist juice processors in effectively achieving a 5-log pathogen reduction in a manner consistent with that knowledge.

This document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance entitled ''Guidance for Industry: Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Reduction'' is being issued as a level 1 draft guidance consistent with GGPs. This draft guidance represents the agency's current recommendations for effectively achieving a 5-log pathogen reduction in juice. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

II. Comments

Interested persons may submit written or electronic comments to the Dockets Management Branch (address above) on the draft guidance by February 19, 2002. However, interested persons may submit written or electronic comments at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The draft guidance and received comments may