

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]

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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Draft Guidance for Industry: Exemptions from the Warning Label Requirement for Juice— Recommendations for Effectively Achieving a 5-Log Reduction; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Reduction."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 This draft guidance describes FDA's current recommendations for effectively achieving a 5-log pathogen reduction in juice.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 GGP's. 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

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 document at the CFSAN home page at <http://www.cfsan.fda.gov>.

Dated: December 14, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4644-N-51]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT:

Mark Johnston, room 7262, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708-4300; TTY number for the hearing- and speech-impaired (202) 708-2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1-800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the

three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for "off-site use only" recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Brian Rooney, Division of Property Management, Program Support Center, HHS, room 5B-41, 5600 Fishers Lane, Rockville, MD 20857; (301) 443-2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1-800-927-7588 for detailed instructions or write a letter to Clifford Taffet at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of

publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: GSA: Mr. Brian K. Polly, Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW., Washington, DC 20405; (202) 501-0052; NAVY: Mr. Charles C. Cocks, Director, Department of the Navy, Real Estate Policy Division, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE., Suite 1000, Washington, DC 20374-5065; (202) 685-9200; (These are not toll-free numbers).

Dated: December 13, 2001.

John D. Garrity,

Director, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 12/21/01

Suitable/Available Properties

Building (by State)

Maryland

Stillpond Housing
521 Round Top Road
Chestertown Co: Queen Anne's MD 21620-
Landholding Agency: GSA
Property Number: 54200140013

Status: Excess
Comment: 1000 sq. ft., most recent use—
residential

GSA Number: 4-U-MD-603

Stillpond Housing
131 Fairview Drive
Chesterview Co: Queen Anne's MD 21620-
Landholding Agency: GSA
Property Number: 54200140014

Status: Excess
Comment: 1000 sq. ft., most recent use—
residential

GSA Number: 4-U-MD-603

Stillpond Housing
100 Farwell Road
Chesterview Co: Queen Anne's MD 21620-
Landholding Agency: GSA
Property Number: 54200140015

Status: Excess
Comment: 1000 sq. ft., most recent use—
residential presence of lead paint

GSA Number: 4-U-MD-603

Stillpond Housing
115 Rolling Road
Chesterview Co: Kent MD 21620-
Landholding Agency: GSA
Property Number: 54200140016

Status: Excess
Comment: 750 sq. ft., most recent use—
residential

GSA Number: 4-U-MD-603

Stillpond Housing
303 Oriole Road