

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 944, 980, and 999

[Docket No. AMS-FV-07-0110; FV07-944/980/999-1 PR]

Fruit, Vegetable, and Specialty Crops—Import Regulations; Proposed Revision to Reporting Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This rule would revise the reporting requirements for imports of commodities regulated under § 608(e) (hereinafter referred to as “8e”) of the Agricultural Marketing Agreement Act of 1937. These changes would require that the inspection certificates generated for each lot of such commodities include the Entry Number from the Customs and Border Patrol (CBP) documentation that accompanies that lot. The proposed changes would also require that importers of raisins, dates, and dried prunes report products exempt from 8e import regulations on AMS Form FV-6—“Importers’ Exempt Commodity Form,” which is the same form that is currently used by importers of all other commodities exempt from 8e import regulations. This proposal also announces the Agricultural Marketing Service’s (AMS) intention to request revisions to a currently-approved information collection for specified exempt import commodities. These changes are intended to streamline the tracking of imported products and provide uniformity in electronic reporting systems used by the industries and the Department of Agriculture (USDA).

DATES: Comments must be received by July 29, 2008. Pursuant to the Paperwork Reduction Act, comment on the information collection burden that would result from this action must be received by July 29, 2008.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments should be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; Fax: (202) 720-8938; or Internet: <http://www.regulations.gov>. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the office of the Docket Clerk during regular business hours, or can be viewed at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Rick Lower or Jared Burnett, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., Stop 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or E-mail: Richard.Lower@usda.gov or JaredK.Burnett@usda.gov.

Small businesses may request information on complying with this regulation by contacting Jay Guerber, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or E-mail: Jay.Guerber@usda.gov.

SUPPLEMENTARY INFORMATION: This proposed rule is issued under section 8e of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the “Act.” Section 8e provides that whenever certain commodities are regulated under Federal marketing orders, imports of those commodities into the United States are prohibited unless they meet the same or comparable grade, size, quality, or maturity requirements as those in effect for the domestically produced commodities. To ensure that these requirements are met, the Act also authorizes USDA to perform inspections and issue inspection certificates for such imported commodities.

Parts 944, 980, and 999 of title 7 of the Code of Federal Regulations (CFR) specify the information that should be included on each inspection certificate issued for regulated imports of fruits, vegetables, and specialty crops,

respectively. Part 999 further specifies which forms importers should use to report to USDA and CBP imports of raisins, dates, and dried prunes that may be exempt from other 8e requirements. Exempt commodities are those which may be imported for purposes such as processing, donation to charitable organizations, or animal feed.

USDA is issuing this rule in conformance with Executive Order 12866.

There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of import regulations issued under section 8e of the Act.

Customs Entry Number

Under the import regulations contained in parts 944, 980, and 999, inspection certificates issued for imports of certain fruits, vegetables, and specialty crops, respectively, must include specific information about the lot being inspected. In addition to stating whether the lot meets the import requirements, such information as the date and place of inspection; the name of the applicant; and the variety, quantity, and identifying marks of the lot inspected are required.

Currently, many inspectors note the customs Entry Number pertaining to the lot being inspected, which is taken from the customs documentation accompanying that lot, in the “Remarks” section or elsewhere on the inspection certificate. The unique Entry Number is generated for each lot by CBP, and may be found on any one of the various forms used to report imported lots of fruit, vegetable, and specialty crop commodities. USDA has found that the Entry Number provides an efficient way to identify individual lots of commodities and to cross-reference all the documents pertaining to each lot. If, for instance, a certain lot fails to meet import regulations when first presented, it may be reworked and presented for inspection a second time. The Entry Number is used to tie both the original and any succeeding inspections to that lot. Additionally, if a lot that fails to meet import requirements is diverted to another market or destroyed, USDA and the importer can use the Entry Number to track that lot through the process.

This rule would make the inclusion of the customs Entry Number on all

pertinent inspection certificates mandatory. Including the Entry Number on inspection certificates would allow importers to more easily demonstrate that the requirements have been met for each lot of regulated commodity imported into the United States. This action would also allow USDA to more easily track imported lots.

Form FV-6

Under the import regulations contained in parts 944, 980, and 999, individual lots of some imported commodities may be exempt from 8e regulations if they are to be used in the processing of other products or consumed through some other exempted use, such as by charitable organizations or as animal feed. However, importers and receivers are still required to declare intent to import those commodities into the United States to CBP and USDA. Most commodities are reported using the generic Form FV-6—"Importer's Exempt Commodity Form."

Exempt imports of two commodities—raisins and dates—are currently reported on forms unique to those commodities. Exempt imports of raisins are reported on Raisin Form No. 1—"Raisins—Section 8e Entry Declaration" and Raisin Form No. 2—"Raisins—Section 8e Certification of Processor of Reseller." Exempt imports of dates are reported on Date Form No. 1—"Dates—Section 8e Entry Declaration" and Date Form No. 2—"Dates—Section 8e Certification of Processor of Reseller."

The 8e regulations for dried prunes were indefinitely suspended on May 27, 2005. The suspended language in § 999.200 specifies that exempt imports of dried prunes are reported on Prune Form No. 1—"Prunes—Section 8e Entry Declaration" and Prune Form No. 2—"Prunes—Section 8e Certification of Processor of Reseller." Those forms would be used if the suspension was lifted in the future.

This rule would change the reporting requirements for imported lots of raisins, dates, and dried prunes that are exempt from other 8e regulations by replacing the commodity-specific import declaration forms described above with the generic Form FV-6. The information collected on Raisin, Date, and Prune Forms 1 and 2 is the same as that collected for other commodities reported on Form FV-6. In its conversion to the use of electronic reporting systems, USDA is adopting the use of an electronic Form FV-6 to monitor imports of regulated commodities that are exempt from the import requirements. Replacing the

existing raisin, date, and dried prune Forms 1 and 2 with the generic Form FV-6 would enable USDA to streamline its operations by collecting information electronically and eliminating unnecessary forms.

Initial Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), AMS has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Import regulations issued under the Act are based on those established under Federal marketing orders.

Small agricultural business firms, which include importers and receivers of these commodities, have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than \$6,500,000. It is likely that the majority of these importers and receivers may be classified as small entities.

This rule would revise the reporting requirements for imports of commodities regulated under section 8e by requiring that the Entry Number from the CBP documentation that accompanies each shipment is included on all inspection certificates pertaining to that lot. Specifically, regulations under part 944 pertaining to imports of avocados, grapefruit, table grapes, kiwifruit, oranges, fresh prunes (plums), and olives; part 980 pertaining to Irish potatoes, onions, and tomatoes; and part 999 pertaining to dates, walnuts, dried prunes, raisins, and filberts (hazelnuts) would be revised.

Requiring that the customs Entry Number be included on the inspection certificates should have very little impact on importers or receivers. The customs documentation containing the Entry Number assigned to each shipment normally accompanies the shipment and should be available at the time of inspection. The inspector would note the Entry Number on the inspection certificate. This is already being done by many inspectors. The inspection certificate is completed by Federal or Federal-State employees. Therefore, there is no regulatory burden on small entities.

The proposed action would further modify part 999 by requiring that importers and receivers of raisins, dates, and dried prunes report products exempt from 8e import regulations on Form FV-6—"Importer's Exempt Commodity Form," instead of the commodity-specific forms currently prescribed for those shipments. Form FV-6 is the same form that is currently used by importers and receivers to report exempted shipments of all other section 8e commodities. There are an estimated 329 importers and receivers of all exempt commodities. These changes are intended to streamline the tracking of imported products and provide uniformity in electronic reporting systems used by the industries and USDA.

It is estimated that 5 importers and 5 receivers of imported raisins for processing, and 5 importers and 10 receivers of imported dates for processing, would be required to replace Raisin and Date Forms No. 1 and 2 with Form FV-6 as a result of this proposed rule. As mentioned above, the domestic order regulations for dried prunes have been suspended. Therefore, the section 8e regulations for imported dried prunes are also suspended. It is unknown how many dried prune importers and receivers would be affected by this rule if the suspension was lifted.

Replacing Raisin, Date, and Prune Forms 1 & 2 with the generic Form FV-6 would eliminate the need to stock various commodity-specific forms. Use of an electronic Form FV-6 would further improve business efficiency for those required to file the reports as well as for USDA.

Raisin, Date, and Prune Forms No. 1 and 2 are currently approved by the Office of Management and Budget (OMB) under OMB No. 0581-0178, "Vegetable and Specialty Crop Marketing Orders" for 48.5 burden hours. Form FV-6 is currently approved by OMB under OMB No. 0581-0167, "Specified Commodities Imported into the United States Exempt from Import Requirements." This rule would remove 48.5 burden hours from OMB No. 0581-0178, and transfer that burden as an increase to OMB No. 0581-0167. This change in burden will be addressed in a revision to a currently approved information collection under OMB No. 0581-0167. The change in burden is explained in the Paperwork Reduction Act section below.

USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this proposed rule.

Interested persons are invited to submit comments on this proposed rule, including the regulatory and

informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/fv/moab.html>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 60-day comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made on this matter.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), AMS announces its intention to submit a revision to a currently-approved information collection.

Title: Specified Commodities Imported Into the United States Exempt from Import Requirements, 7 CFR Parts 944, 980, and 999.

OMB Number: 0581-0167.

Type of Request: Revision.

Abstract: Section 8e of the Act requires that whenever the Secretary of Agriculture issues grade, size, quality, or maturity regulations under domestic marketing orders for certain commodities, the same or comparable regulations on imports of those commodities must be issued. Import regulations apply only during those periods when domestic marketing order regulations are in effect.

Currently, the following commodities are subject to Section 8e import regulations: Avocados, dates (other than dates for processing), hazelnuts, grapefruit, table grapes, kiwifruit, olives (other than Spanish-style olives), onions, oranges, Irish potatoes, dried prunes (suspended), fresh prunes, raisins, tomatoes, and walnuts. However, imports of these commodities are exempt from such requirements if they are imported for such outlets as processing, charity, animal feed, seed, and distribution to relief agencies when those outlets are exempt under the applicable marketing orders.

Safeguard procedures in the form of importer and receiver reporting requirements are used to ensure that the imported commodities are shipped to authorized exempt outlets. Reports required under the safeguard procedures are similar to the reports currently required by most domestic marketing orders. The following import regulations require importers and receivers of imported fruit, vegetable, and specialty

crops to submit reports: (1) Fruits; import regulations (7 CFR part 944.350); (2) vegetables; import regulations (7 CFR part 980.501); and (3) Specialty crops; import regulations (7 CFR part 999.500).

When required to do so under the above regulations, an importer wishing to import commodities for exempt purposes completes, prior to importation, an "Importer's Exempt Commodity Form," Form FV-6, which is a four-part form. The first copy is presented to U.S. Customs and Border Protection, Department of Homeland Security. The second copy is filed with the Marketing Order Administration Branch (MOAB) of the Fruit and Vegetable Programs, AMS, within two days after the commodity enters the United States. The third copy of the form accompanies the exempt shipment to its intended destination. The receiver certifies that the commodity has been received and that it will be utilized for authorized exempt purposes. The receiver then files the third copy with MOAB within two days after receiving the commodity. The fourth copy is retained by the importer.

USDA utilizes this information to ensure that imported goods destined for exempt outlets are given no less favorable treatment than that afforded domestic goods destined for such exempt outlets. These exemptions are consistent with Section 8e import regulations under the Act.

Form FV-6 requires the minimum amount of information necessary to effectively carry out the requirements of the Act, and its use is necessary to fulfill the intent of the Act and to administer Section 8e compliance activities.

USDA is currently in the process of converting the four-part Form FV-6 to an electronic format. It is expected that use of the electronic reporting system will reduce the time needed to complete and submit Form FV-6.

The information collection package for which this notice of extension and revision is provided contains one other form, "Civil Penalty Stipulation Agreement," Form FV-7, which was not addressed in this rule. There are no proposed revisions to Form FV-7. The sole requirement for this form is the respondent's signature. Therefore, there is no burden associated with it.

The information collected through this package is used primarily by authorized representatives of USDA, including AMS' Fruit and Vegetable Programs' regional and headquarters staff.

Estimate of Burden: The public reporting burden for this information collection is estimated to average 0.08 hours per response.

Respondents: Importers and receivers of exempt commodities.

Estimated Number of Respondents: 329.

Estimated Total Annual Responses: 9,131.

Estimated Number of Responses per Respondent: 27.75.

Estimated Total Annual Burden on Respondents: 755.69 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of USDA functions, including whether the information will have practical utility; (2) the accuracy of USDA's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments on the information collection should reference OMB No. 0581-0167 and "Specified Commodities Imported into the United States Exempt from Import Requirements." Comments should be sent to the Docket Clerk at the previously-mentioned address or submitted via the Internet at <http://www.regulations.gov>.

All responses to this notice will be summarized and included in the request for OMB approval. All comments received will become a matter of public record and will be available for public inspection during regular business hours at the same address or at <http://www.regulations.gov>.

AMS is committed to compliance with the Government Paperwork Elimination Act, which requires government agencies in general to provide the public with the option of submitting information or transacting business electronically to the maximum extent possible.

List of Subjects

7 CFR Part 944

Avocados, Food grades and standards, Grapefruit, Grapes, Imports, Kiwifruit, Limes, Olives, Oranges.

7 CFR Part 980

Food grades and standards, Imports, Marketing agreements, Onions, Potatoes, Tomatoes.

7 CFR Part 999

Dates, Filberts, Food grades and standards, Imports, Nuts, Prunes,

Raisins, Reporting and recordkeeping requirements, Walnuts.

For the reasons set forth above, 7 CFR parts 944, 980, and 999 are proposed to be amended as follows:

1. The authority citation for 7 CFR parts 944, 980, and 999 continues to read as follows:

Authority: 7 U.S.C. 601–674.

PART 944—FRUITS; IMPORT REGULATIONS

2. In § 944.400, paragraph (d) is amended by redesignating paragraphs (d)(3) through (d)(7) as paragraphs (d)(4) through (d)(8) and adding a new paragraph (d)(3) to read as follows:

§ 944.400 Designated inspection services and procedure for obtaining inspection and certification of imported avocados, grapefruit, kiwifruit, oranges, prune variety plums (fresh prunes), and table grapes regulated under section 8e of the Agricultural Marketing Agreement Act of 1937, as amended.

(d) * * *

(3) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

3. In § 944.401, paragraph (i) is amended by redesignating paragraphs (i)(3) through (i)(8) as paragraphs (i)(4) through (i)(9) and adding a new paragraph (i)(3) to read as follows:

§ 944.401 Olive Regulation 1.

(i) * * *

(3) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

PART 980—VEGETABLES; IMPORT REGULATIONS

4. In § 980.1, paragraph (g)(4) is amended by redesignating paragraphs (g)(4)(iii) through (g)(4)(vii) as paragraphs (g)(4)(iv) through (g)(4)(viii) and adding a new paragraph (g)(4)(iii) to read as follows:

§ 980.1 Import Regulations; Irish potatoes.

(g) * * *

(4) * * *

(iii) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

5. In § 980.117, paragraph (f)(5) is amended by redesignating paragraphs (f)(5)(iii) through (f)(5)(vii) as paragraphs (f)(5)(iv) through (f)(5)(viii) and adding a new paragraph (f)(5)(iii) to read as follows:

§ 980.117 Import Regulations; onions.

(f) * * *

(5) * * *

(iii) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

6. In § 980.212, paragraph (f)(5) is amended by redesignating paragraphs (f)(5)(iii) through (f)(5)(vii) as paragraphs (f)(5)(iv) through (f)(5)(viii) and adding a new paragraph (f)(5)(iii) to read as follows:

§ 980.212 Import Regulations; Tomatoes.

(f) * * *

(5) * * *

(iii) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

PART 999—SPECIALTY CROPS; IMPORT REGULATIONS

§ 999.1 [Amended]

7. Section 999.1 is amended by:

A. Redesignating paragraphs (c)(2)(iii) through (c)(2)(v) as paragraphs (c)(2)(iv) through (c)(2)(vi) and adding a new paragraph (c)(2)(iii).

B. Removing the phrase “(c)(2)(iv)” in paragraph (e)(1) and adding the phrase “(c)(2)(v)” in its place.

C. Revising paragraph (e)(2).

D. Revising paragraph (e)(3).

E. Removing the phrase “Date Form No. 2” in paragraph (e)(4) and adding the phrase “Form FV–6” in its place.

F. Removing the phrase “Date Form No. 2 ‘Dates for Processing—Section 8e Certification of Processor or Reseller’” in paragraph (f) and adding the phrase “Form FV–6—‘Importer’s Exempt Commodity Form’” in its place.

G. Removing the phrase “Date Form No. 1 ‘Dates—Section 8e Entry Declaration’”, in the first sentence in paragraph (g), and adding the phrase “Form FV–6—‘Importer’s Exempt Commodity Form’” in its place.

H. Removing the phrase “Date Form No. 1”, from the second sentence in paragraph (g), and adding the phrase “Form FV–6” in its place.

The new additions read as follows:

§ 999.1 Regulation governing the importation of dates.

(c) * * *

(2) * * *

(iii) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

(e) * * *

(2) *Dates for processing and dates prepared or preserved-importation.* Any person may import dates for processing and dates prepared or preserved exempt from the grade inspection, and certification requirements of this section if the importer first files as a condition of such importation an executed “Form FV–6—‘Importer’s Exempt Commodity Form.’” The importer shall promptly transmit a copy of the executed “Form FV–6” to the Fruit and Vegetable Division.

(3) *Dates for processing—Sale by importer.* No importer or other person may import, sell, or use any dates for processing other than for use as set forth in paragraph (a)(4) of this section or as otherwise permitted by this section. Each importer of dates for processing shall obtain from each purchaser, no later than the time of delivery to such purchaser, and file with the Fruit and Vegetable Division not later than the fifth day of the month following the month in which the dates were delivered, and executed “Form FV–6.”

8. In § 999.100, paragraph (c)(2) is amended by redesignating paragraphs (c)(2)(iv) and (c)(2)(v) as paragraphs (c)(2)(v) and (vi) and adding a new paragraph (c)(2)(iv) to read as follows:

§ 999.100 Regulations governing imports of walnuts.

(c) * * *

(2) * * *

(iv) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

9. In Part 999, the suspension of § 999.200 is lifted and amended as follows:

A. Removing the phrase “Prune Form No. 1 Prunes—Section 8e Entry Declaration” in paragraph (b)(5) and adding the phrase “Form FV–6—‘Importer’s Exempt Commodity Form’” in its place.

B. Redesignating paragraphs (c)(2)(iii) through (c)(2)(v) as paragraphs (c)(2)(iv) through (c)(2)(vi) and adding a new paragraph (c)(2)(iii).

C. Removing the phrase “‘Prunes—Section 8e Entry Declaration,’ prescribed in paragraph (e)(2) of this section as Prune Form No. 1” in the second sentence of paragraph (e)(1), and add the phrase “Form FV–6—‘Importer’s Exempt Commodity Form;’” in its place.

D. Removing the phrase “‘Prunes—Section 8e Certification of Processor or Reseller’ prescribed in paragraph (e)(3) of this section as Prune Form No. 2” in the fifth sentence of paragraph (e)(1),

and adding the phrase “Form FV-6—Importer’s Exempt Commodity Form” in its place.

E. Removing paragraphs (e)(2) and (e)(3).

F. Redesignating paragraph (e)(4) as paragraph (e)(2).

G. Revising newly redesignated paragraph (e)(2).

The new additions read as follows:

§ 999.200 Regulation governing the importation of prunes.

* * * * *

(c) * * *

(2) * * *

(iii) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

* * * * *

(e) * * *

(2) *Manufacturing Grade Substandard Prune—sale by other than importer.* Each wholesaler or other reseller of manufacturing grade substandard prunes should, for his protection, obtain from each purchaser and hold in his files an executed Form FV-6—“Importer’s Exempt Commodity Form” covering each sale during the calendar year.

* * * * *

§ 999.200 [Suspended]

10. Suspend § 999.200 indefinitely.

§ 999.300 [Amended]

11. Section 999.300 is amended by:

A. Redesignating paragraph (c)(2)(iv) through (c)(2)(vi) as paragraphs (c)(2)(v) through (c)(2)(vii) and adding a new paragraph (c)(2)(iv).

B. Removing the phrase “Raisins—Section 8e Entry Declaration” prescribed in paragraph (e)(2)(i) of this section as ‘Raisin Form No. 1’, in the second sentence of paragraph (e)(2), and adding the phrase “Form FV-6—Importer’s Exempt Commodity Form” in its place.

C. Removing the phrase “Raisins—Section 8e Certification of Processor or Reseller,” prescribed in paragraph (e)(2)(ii) of this section as ‘Raisin Form No. 2’, in the fifth sentence of paragraph (e)(2) and adding the phrase “Form FV-6” in its place.

D. Removing the phrase “Raisin Form No. 2” from the seventh sentence of paragraph (e)(2) and adding the phrase “Form FV-6” in its place.

E. Removing paragraphs (e)(2)(i) and (e)(2)(ii).

The additions read as follows:

§ 999.300 Regulation governing importation of raisins.

* * * * *

(c) * * *

(2) * * *

(iv) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

* * * * *

13. In § 999.400, paragraph (c)(3) is amended by redesignating paragraphs (c)(3)(iv) through (c)(3)(vi) as paragraphs (c)(3)(v) through (c)(3)(vii) and adding a new paragraph (c)(3)(iv) to read as follows:

§ 999.400 Regulation governing the importation of filberts.

* * * * *

(c) * * *

(3) * * *

(iv) The customs Entry Number pertaining to the lot or shipment covered by the certificate;

* * * * *

Dated: May 22, 2008.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E8-11924 Filed 5-29-08; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA-2008-N-0273]

Medical Devices; Radiology Devices; Reclassification of Full Field Digital Mammography System

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the full field digital mammography (FFDM) system from class III (premarket approval) to class II (special controls). The device type is intended to produce full field digital x-ray images of the breast. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance document entitled “Class II Special Controls Guidance Document: Full Field Digital Mammography System” that would serve as the special control for the device, if FDA reclassifies this device type.

DATES: Submit written or electronic comments by August 28, 2008. See section X of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2008-N-0273, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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 Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, 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.regulations.gov> 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: Robert A. Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3666.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by (among other amendments) the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), the Safe Medical Devices Act of 1990 (Public Law 101-629), and the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), established a comprehensive