communicate scientific or technical information to NASA.

§ 1207.80 Scope of subpart

This subpart provides guidance to former NASA government employees who are subject to the restrictions of Title V of the Ethics of Government Act of 1978, as amended, and who want to communicate scientific or technical information to NASA.

§ 1207.801 Exemption for scientific and technological communications.

(a) Whenever a former government employee who is subject to the constraints of post-employment conflict of interest, 18 U.S.C. 207, wishes to communicate with NASA under the exemption in section 207(f) for the making of a communication solely for the purpose of furnishing scientific or technological information, he or she shall state to the NASA employee contracted, the following information:

(1) That he or she is a former government employee subject to the post employment restrictions of 18 U.S.C. 207 (a), (b), or (c)—specify which;

(2) That he or she worked on certain NASA programs—enumerate which; and

(3) That the communication is solely for the purpose of furnishing scientific or technological information.

(b) If the former government employee has questions as to whether the communication comes within the scientific and technological exemption, he or she should contact the General Counsel, the designated agency ethics official.

Dale D. Myers,

Deputy Administrator.

January 23, 1989.

[FR Doc. 89-1880 Filed 1-26-89; 8:45 am]

BILLING CODE 7510-01-M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 770, 772 and 778

[Docket No. 81149-8249]

Revision of Enforcement and Administrative Proceedings

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Interim rule with request for comments.

SUMMARY: The agency is revising Parts 770 (Export Licensing General Policy), 772 (Individual Validated Licenses) and 788 (Administrative Proceedings) of the Export Administration Regulations (Parts 770, 772 and 788, Title 15, Code of Federal Regulations). These revisions are limited to those changes mandated by the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100-418, 101 Stat. 1107), which amended and extended the Export Administration Act of 1979 (50 U.S.C. app. §§ 2401-2420 (1982 and Supp. III 1985)) (the Act). These changes implement both new and revised statutory provisions concerning violations and set forth procedures governing the denial of export privileges for persons convicted of violating specified statutes.

DATES: Interim rule effective January 27, 1989; comments must be received on or before March 28, 1989.

ADDRESS: Written comments (six copies when possible) should be sent to: Daniel C. Hurley, Jr., Attorney-Advisor, Office of Chief Counsel for Export Administration, U.S. Department of Commerce, Room H-3329, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Daniel C. Hurley, Jr., Office of the Chief Counsel for Export Administration, 202/377-5311.

SUPPLEMENTARY INFORMATION: This rule revises the Export Administration Regulations to reflect changes in the Export Administration Act (for example, prescribes the method by which denials of export privileges to persons convicted of specified offenses may be extended to related persons), to conform specific procedural provisions to the Export Administration Act, and to reflect organizational changes within the Bureau of Export Administration.

The rule notes the availability of judicial review of final agency decisions in export control cases. Pursuant to Section 13(c) of the Act, the written order of the Secretary [1] is the final agency action, except that the charged party may, within 15 days after the order is issued, appeal the order to the United States Court of Appeals for the District of Columbia Circuit which may, while the appeal is pending, stay the order of the Secretary.

The rule also implements statutory changes governing temporary denial orders. Pursuant to Section 13(d) of the Act, the period for which temporary denial orders may be issued or renewed has been extended from 60 days to 180 days. In addition, a person subject to an order of the Under Secretary affirming, in whole or in part, the issuance of a temporary denial order may, within 15 days after the order is issued, appeal the order to the United States Court of Appeals for the District of Columbia Circuit.

Rulemaking Requirements

1. Because this rule concerns a foreign and military affairs function of the United States, it is not a rule or regulation within the meaning of Section 1(a) of Executive Order 12291, and it is not subject to the requirements of that Order. Accordingly, no preliminary or final Regulatory Impact Analysis has to be or will be prepared.

2. This rule does not contain a collection of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553), or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility analysis has to be or will be prepared.

5. Section 13(a) of the Export Administration Act of 1979 (EAA), as amended (50 U.S.C. app. 2412(a)), exempts this rule from all requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring publication of a notice of proposed rulemaking, an opportunity for public comment, and a delay in effective date. This rule is also exempt from those APA requirements because it involves a foreign and military affairs function of the United States. Section 13(b) of the EAA does not require that this rule be published in proposed form because this rule does not impose a new control. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

However, consistent with the intent of Congress set forth in Section 13(b) of the Act to provide public participation in rulemaking, these regulations are issued in interim form and comments will be considered in developing final regulations.

The period for submission will close March 28, 1989. All comments received before the close of the comment period will be considered by the Department in the development of final regulations.

[1] Pursuant to Department Organization Order 10-16, effective March 22, 1988, the Secretary's authority to issue final orders in administrative proceedings was delegated to the Under Secretary for Export Administration.

While comments received after the end of the comment period will be considered if possible, their consideration cannot be assured. Public comments that are accompanied by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason will not be accepted. Such comments and materials will be returned to the submitter and will not be considered in the development of final regulations.

All public comments on these regulations, whenever received, will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, comments in written form are preferred. If oral comments are received, a written summary will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will not be made available for public inspection.

The public record concerning these regulations will be maintained in the Bureau of Export Administration Freedom of Information Records Inspection Facility, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Room H-4886, Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in Part 4 of Title 15 of the Code of Federal Regulations. Information about the inspection and copying of records at the facility may be obtained from Ms. Margaret Cornejo, the Bureau of Export Administration Freedom of Information Officer, at the above address or by calling 202/377-2593.

List of Subjects in 15 CFR Part 770

Exports, Reporting and recordkeeping requirements.

List of Subjects in 15 CFR Part 772

Exports, Validated License and recordkeeping requirements.

List of Subjects in 15 CFR Part 788

Administrative practice and procedure. Denial of export privileges. Exports, Temporary denial of export privileges.

Accordingly, Parts 770, 772 and 788 of the Export Administration Regulations (15 CFR Parts 768-799) are amended as follows:

1. The authority citations for Parts 770 and 772 are revised to read as follows:

Authority: Pub. L. 96-72, 93 Stat. 503 (50 U.S.C. app. 2401 *et seq.*), as amended by Pub. L. 97-145 of December 29, 1981, 95 Stat. 1727, by Pub. L. 99-64 of July 12, 1985, 99 Stat. 120, and by Pub. L. 100-418 of August 23, 1988, 102 Stat. 1107; E.O. 12525 (3 CFR 377 (1986)) E.O. 12214 (3 CFR 256 (1981)), and E.O. 12002 (3 CFR 133 (1978)).

2. 15 CFR Part 770 is amended by revising § 770.15(a) to read as follows:

§ 770.15 Administrative action denying permission to apply for or use export licenses.

(a) *General.* The Director, Office of Export Licensing, in consultation with the Director, Office of Export Enforcement, may deny permission to apply for or use any export license, including any general license, to any person who has been convicted of a violation of the Export Administration Act, or any regulation, license, or order issued under the Act; any regulation, license or order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701-1706); 18 U.S.C. 793, 794 or 798; Section 4(b) of the Internal Security Act of 1950 (50 U.S.C. 783(b)), or Section 38 of the Arms Export Control Act (22 U.S.C. 2778).

* * * * *

§ 770.15 [Amended]

3. 15 CFR Part 770 is amended by redesignating existing paragraphs (c) through (f) of § 770.15 as paragraphs (d) through (g), and by adding new § 770.15(c) to read as follows:

* * * * *

(c) *Criteria.* In determining whether to deny U.S. export privileges to a person previously convicted of one or more of the statutes set forth in paragraph (a) of this section, the Director, Office of Export Licensing may take into consideration any relevant information, including, but not limited to, the seriousness of the offense involved in the criminal prosecution, the nature and duration of the criminal sanctions imposed, and whether the person has undertaken any corrective measures.

* * * * *

§ 770.15 [Amended]

4. 15 CFR Part 770 is amended by adding § 770.15(h) to read as follows:

* * * * *

(h) *Applicability to related person.* The Director, Office of Export Licensing, in consultation with the Director, Office of Export Enforcement, may, through the Chief Counsel for Export Administration, notify any person related through affiliation, ownership, control, or position or responsibility to any person denied export privileges under paragraph (a) of this section, of his intent to deny that person permission to apply for or use any export license, including any general license. Such person so notified may request a hearing by filing a request for a hearing with the Office of The Administrative Law Judge, Room H6716, 14th Street and Constitution Avenue NW., Washington, DC 20230 and by serving a copy of the request for a hearing on the Office of the Chief Counsel for Export Administration. The sole issue to be raised and ruled on under this paragraph is the question whether such person so notified is related to any person denied export privileges under paragraph (a) of this section, and not the scope or duration of the underlying denial. The provisions of Part 788 of this chapter shall apply to any hearing requested under this paragraph (h).

§ 772.1 [Amended]

5. 15 CFR Part 772 is amended by revising § 772.1(h) to read as follows:

§ 772.1 General provisions.

* * * * *

(h) (1) *Administrative action revoking export licenses.* The Director, Office of Export Licensing, in consultation with the Director, Office of Export Enforcement, may revoke any export license, including any general license, issued or otherwise available to any person who has been convicted of a violation of the Export Administration Act, or any regulation, license, or order issued under the Act; any regulation, license, or order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701-1706); 18 U.S.C. 793, 794 or 798; section 4(b) of the Internal Security Act of 1950 (50 U.S.C. 783(b)), or section 38 of the Arms Export Control Act (22 U.S.C. 2778).

* * * * *

6. The authority citations for 15 CFR Part 788 are revised to read as follows:

Authority: Pub. L. 96-72 of September 29, 1979, 93 Stat. 503 (50 U.S.C. app. 2401 *et seq.*), as amended by Pub. L. 97-145 of December 29, 1981, 95 Stat. 1727, by Pub. L. 99-64 of July 12, 1985, 99 Stat. 120, and by Pub. L. 100-418 of August 23, 1988, 102 Stat. 1107; E.O. 12525 (3 CFR 377 (1986)), E.O. 12214 (3 CFR 256 (1981)), and E.O. 12002 (3 CFR 133 (1978)).

§ 788.19 [Amended]

7. 15 CFR Part 788 is amended by substituting the number "180" in place of "60" where it appears in § 788.19(b)(4).

§ 788.19 [Amended]

8. 15 CFR Part 788 is amended by substituting the number "180" in place of "60" where it appears in § 788.19(d)(1).

§ 788.19 [Amended]

9. 15 CFR Part 788 is amended by revising the last sentence in § 788.19(e)(5) to read as follows:

* * * * *

(e) * * *

(5) *Final decision.* * * * The Under Secretary's written order shall be final and is not subject to judicial review, except as provided in § 788.19(g).

* * * * *

§ 788.19 [Amended]

10. 15 CFR Part 788 is amended by adding new paragraph 788.19(g) to read as follows:

* * * * *

(g) *Judicial review.* The Under Secretary's written order may be appealed to the United States Court of Appeals for the District of Columbia pursuant to 50 U.S.C. app. 2412(d)(3).

§ 788.23 [Amended]

11. 15 CFR Part 788 is amended by removing the last sentence in § 788.23(c).

§ 788.23 [Amended]

12. 15 CFR Part 788 is amended by adding a new paragraph (e) to § 788.23 to read as follows:

* * * * *

(e) The Under Secretary's written order may be appealed within 15 days to the United States Court of Appeals for the District of Columbia pursuant to 50 U.S.C. app. 2412(c)(3).

Dated: January 18, 1989.

Michael E. Zacharia,

Assistant Secretary for Export Administration.

[FR Doc. 89-1797 Filed 1-26-89; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 107

[Docket No. 87N-0082]

Infant Formula Recall Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is, in accordance with the 1986 Infant Formula amendments to the Federal Food, Drug, and Cosmetic Act (the act), amending its recall regulations for infant formulas. These amendments: (1) Specify recall procedures that shall be used by manufacturers in removing from the marketplace adulterated or misbranded infant formula that the agency has determined may present a risk to human health; (2) require a manufacturer recalling an infant formula that presents a risk to human health to request that each retail establishment at which such infant formula is sold or available for sale post a notice of such recall; and (3) establish infant formula distribution records retention requirements.

EFFECTIVE DATE: March 28, 1989.

FOR FURTHER INFORMATION CONTACT: Curtis E. Coker, Jr., Center for Food Safety and Applied Nutrition (HFF-314), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0024.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 13, 1987 (52 FR 30171), FDA proposed to amend its recall regulations for infant formulas to: (1) Specify recall procedures that shall be used by manufacturers in removing from the marketplace adulterated and misbranded infant formula that the agency has determined may present a risk to human health; (2) require a manufacturer recalling an infant formula that presents a risk to human health to request that each retail establishment at which such infant formula is sold or available for sale post a notice of such recall; and (3) establish infant formula distribution records retention requirements. FDA proposed these amendments to reflect changes in the infant formula provisions of the Federal Food, Drug, and Cosmetic Act (the act) contained in the Drug Enforcement Education and Control Act of 1986 (Pub. L. 99-570) (the 1986 amendments).

Interested persons were given until October 13, 1987, to comment on the proposal. FDA received comments from a trade association and a consumer group in support of the proposal. Both organizations suggested minor modifications to the proposed rule. The consumer group also commented on certain historical background information in the proposal's preamble. The agency is not responding to these comments on the historical background because they do not have a direct bearing on the proposed rule.

FDA initially proposed codifying the infant formula regulations in Part 7—Enforcement Policies (21 CFR Part 7), consisting of §§ 7.68 to 7.76. The agency has determined that because they specifically govern recalls of infant formulas and, because, in the case of a hazard to health, such recalls are mandatory, these regulations are more appropriately codified in Part 107—Infant Formula (21 CFR Part 107), consisting of §§ 107.200 to 107.280. The section headings have remained essentially the same. A summary of the pertinent comments and the agency's responses are as follows:

1. One comment requested that FDA revise the language in § 107.230(d) (21 CFR 107.230(d)) to require a 15-day limit on the time for displaying a notice of recall at retail establishments. (Section 107.230(d) was originally proposed as § 7.71(d) (21 CFR 7.71(d).) In support of this suggestion, the comment stated that a uniform and definite posting period would be advantageous because it would eliminate the need for two communications from the manufacturer to the retailer, and that two communications could create an opportunity for confusion.

Another comment opposed limiting the time period for the display of this notice and stated that the required posting should be for a substantially longer period of time, although the comment did not suggest a specific alternative. In support of its opposition to the 15-day period, this comment stated that parents often buy infant formula in large quantities and, therefore, could miss a recall notice displayed for only a 15-day period.

The agency does not agree with either comment. FDA's experience is that each recall is unique; some recalls are completed before 15 days and others require a substantially longer time to complete. (FDA's current policy is that a recall of an infant formula is complete when the recalling firm has actually impounded all outstanding product that could reasonably be expected to be recovered.)

FDA believes that requiring an infant formula recall notice to be posted at a retail establishment after completion of the recall could cause confusion and concern to consumers and could have an unnecessary adverse economic impact on the industry and the recalling firm, as well as consumers, without achieving any public health benefit. Likewise, FDA believes that the public health would not be adequately protected by permitting such recall notices to be removed before completion of the recall. For these reasons, the agency has concluded that manufacturers should be required to request that recall notices be posted at retail establishments for the duration of the recall. Accordingly, § 107.230(d) remains as originally proposed.

2. One comment also suggested amending proposed § 107.240(a) to make it clear that inconsequential or technical violations of the act, such as a minor typographical error on a label or insignificant deviations in current good manufacturing practices, need not be

reported to FDA. (Section 107.240(a) was originally proposed as § 7.72(a) (21 CFR 7.72(a).) In support, this comment cited statements by the amendments' cosponsors, Senators Hatch and Metzenbaum, made at the time the legislation was enacted. Another comment opposed this clarification and stated that FDA should be made aware of all deviations whether or not recall of a product results. The first comment also suggested a change in the format of § 107.240(a) to create two paragraphs in order to clarify that there are two separate instances in which notification to FDA is required.

The agency does not believe that the requested modification in the language of § 107.240(a) is warranted. The plain language of the notification provision of the 1986 amendments (section 412(e)(1) of the act, 21 U.S.C. 350a(e)(1) requires that a manufacturer with the requisite knowledge notify FDA of any infant formula that may not provide the required nutrients or that may otherwise be adulterated or misbranded; no exceptions from such notification for so-called technical violations are set forth in the statute. This plain language in the statute is controlling, in the absence of a clearly expressed legislative intent to the contrary. *United States* v. *Turkette*, 452 U.S. 576, 580 (1981).

In this case, the legislative history of the amendments, when read as a whole, expresses no clear intention by Congress to limit the types of adulteration or misbranding for which an infant formula manufacturer is required to notify FDA. In fact, Senator Hatch's complete remarks show that he was principally concerned about limiting the instances in which recalls, not notification to FDA, would be required. (132 Cong. Rec. S14047 (daily ed. September 27, 1986).) The final rule is consistent with both the plain language of the statute and the amendments' legislative history in that FDA will require an infant formula manufacturer to conduct a recall only when the infant formula presents a risk to human health.

Although FDA is declining at this time to limit by regulation the instances of adulteration and misbranding that must be reported to FDA pursuant to § 107.240(a), the agency intends to monitor the notifications made to the agency under § 107.240(a) to determine whether any limitations should be established in the future, either by guideline or further regulation.

In addition, FDA notes that even if a manufacturer elects to remove from the marketplace an infant formula that is adulterated or misbranded in only a technical way, such market removal does not constitute a recall subject to this subpart. Under longstanding agency policy, a firm's removal from the market of a product that is violative in some minor way (e.g., inconsequential deviations from good manufacturing practices), but would not be subject to seizure under current agency policy, is deemed to be a market withdrawal and not a recall. To constitute a recall, the subject product must be both violative and actionable (21 CFR 7.3(g)). Thus, even though this rule may require an infant formula manufacturer to notify FDA of a technical or minor instance of adulteration or misbranding, such notification will not necessarily trigger an FDA-required or even a firm-initiated recall. Accordingly, FDA believes that § 107.240(a) accurately implements this part of the 1986 amendments. For this reason, the language of § 107.240(a) remains as originally proposed.

FDA does believe, however, that the change in format recommended for § 107.240 has merit and, thus, has implemented that suggestion in the final regulation. Furthermore, in order to clarify the status of market recalls under this rule, FDA is revising § 107.210 (originally proposed as § 7.69) to state clearly that a manufacturer's voluntary removal from the market of an infant formula that is adulterated or misbranded in only a minor way and that would not be subject to agency legal action constitutes a market withdrawal within the meaning of 21 CFR 7.3(j). As revised, § 107.210(b) states that manufacturers conducting a market withdrawal may, but are not required to, adhere to the requirements of this subpart pertaining to product recalls. Revised § 107.210(b) also clarifies that, as discussed above, a manufacturer conducting a market withdrawal must nevertheless notify FDA of the adulteration or misbranding, as required by § 107.240(a). FDA does not consider this revision of § 107.210 to be a substantive change requiring reproposal because the preamble to the proposed rule clearly indicated the agency's intent to exclude market withdrawals from the recall requirements. ("As revised, new § 7.69 [now § 107.210] would apply to an infant formula that has been distributed, that does not present a human health risk, but that is otherwise in violation of the laws and regulations administered by FDA and against which the agency could initiate legal or regulatory action." (See 52 FR 30171 and 30172; August 13, 1987.))

In addition to the modifications in the final rule discussed above, FDA is making minor editorial changes in §§ 107.200, 107.220, 107.230, 107.240, and 107.250 to achieve greater clarity and consistency in the final rule. (These sections were originally proposed as §§ 7.68, 7.70, 7.71, 7.72, and 7.73, respectively.) FDA has determined that none of these modifications initiated by the agency is a substantive change that requires reproposal of the regulation.

Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule of August 13, 1987 (52 FR 3017). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

Economic Impact

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Felxibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as defined by the Order. The agency has not received any new information or comments that would alter its previous determination.

Paperwork Reduction Act of 1980

Section 107.280 of this final rule contains collection of information requirements that were submitted for review and approval to the Director, Office of Management and Budget (OMB), as required by section 3504(h) of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910–0188.

List of Subjects in 21 CFR Part 107

Food labeling, Infants and children, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 107 is amended as follows:

PART 107—INFANT FORMULA

1. The authority citation for 21 CFR Part 107 continues to read as follows:

Authority: Secs. 201 (n) and (aa), 403 (a) and (j), 412, 701, 52 Stat. 1041 as amended, 1047–1048 as amended, 1055–1056 as amended, 94 Stat. 1190–1193 (21 U.S.C. 321 (n) and (aa), 343 (a) and (j), 350a, 371); 21 CFR 5.11; § 107.100 issued only under secs. 201(aa), 412, 701(a), 52 Stat. 1055, 94 Stat. 1190–1193 (21 U.S.C. 321(aa), 350a, 371(a)); 21 CFR 5.11; Subparts A and C are issued under secs. 201 (n) and (aa), 403(a), 412, 701(a), 52 Stat. 1041 as amended, 1047 as amended, 1055, 94 Stat. 1190 (21 U.S.C. 321 (n) and (aa), 343(a), 350a, 371(a)); 21 CFR 5.11.

2. A new Subpart E consisting of §§ 107.200 through 107.280 is added to read as follows:

Subpart E—Infant Formula Recalls

Sec.

107.200 Food and Drug Administration-required recall.
107.210 Firm-initiated product removals.
107.220 Scope and effect of infant formula recalls.
107.230 Elements of an infant formula recall.
107.240 Notification requirements.
107.250 Termination of an infant formula recall.
107.260 Revision of an infant formula recall.
107.270 Compliance with this subpart.
107.280 Records retention.

Subpart E—Infant Formula Recalls

§ 107.200 Food and Drug Administration-required recall.

When the Food and Drug Administration determines that an adulterated or misbranded infant formula presents a risk to human health, a manufacturer shall immediately take all actions necessary to recall that formula, extending to and including the retail level, consistent with the requirements of this subpart.

§ 107.210 Firm-initiated product removals.

(a) If a manufacturer has determined to recall voluntarily from the market an infant formula that is not subject to § 107.200 but that otherwise violates the laws and regulations administered by the Food and Drug Administration (FDA) and that would be subject to legal action, the manufacturer, upon prompt notification to FDA, shall administer such voluntary recall consistent with the requirements of this subpart.

(b) If a manufacturer has determined to withdraw voluntarily from the market an infant formula that is adulterated or misbranded in only a minor way and that would not be subject to legal action, such removal from the market is deemed to be a market withdrawal, as defined in § 7.3(j) of this chapter. As required by § 107.240(a), the manufacturer shall promptly notify FDA of such violative formula and may, but is not required to, conduct such market withdrawal consistent with the requirements of this subpart pertaining to product recalls.

§ 107.220 Scope and effect of infant formula recalls.

(a) The requirements of this subpart apply:

(1) When the Food and Drug Administration has determined that it is necessary to remove from the market a distributed infant formula that is in violation of the laws and regulations administered by the Food and Drug Administration and that poses a risk to human health; or

(2) When a manufacturer has determined that it is necessary to remove from the market a distributed infant formula that:

(i) Is no longer subject to the manufacturer's control;

(ii) Is in violation of the laws and regulations administered by the Food and Drug Administration and against which the agency could initiate legal or regulatory action; and

(iii) Does not present a human risk.

(b) The Food and Drug Administration will monitor continually the recall action and will take appropriate actions to ensure that the violative infant formula is removed from the market.

§ 107.230 Elements of an infant formula recall.

A recalling firm shall conduct an infant formula recall with the following elements:

(a) The recalling firm shall evaluate in writing the hazard to human health associated with the use of the infant formula. This health hazard evaluation shall include consideration of any disease, injury, or other adverse physiological effect that has been or that could be caused by the infant formula and of the seriousness, likelihood, and consequences of the diseases, injury, or other adverse physiological effect. The Food and Drug Administration will conduct its own health hazard evaluation and promptly notify the recalling firm of the results of that evaluation if the criteria for recall under § 107.200 have been met.

(b) The recalling firm shall devise a written recall strategy suited to the individual circumstances of the particular recall. The recall strategy shall take into account the health hazard evaluation and specify the following: The extent of the recall; if necessary, the public warning to be given about any hazard presented by the infant formula; the disposition of the recalled infant formula; and the effectiveness checks that will be made to determine that the recall is carried out.

(c) The recalling firm shall promptly notify each of its affected direct accounts about the recall. The format of a recall communication shall be distinctive, and the content and extent of a recall communication shall be commensurate with the hazard of the infant formula being recalled and the strategy developed for the recall. The recall communication shall instruct consignees to report back quickly to the recalling firm about whether they are in possession of the recalled infant formula and shall include a means of doing so. The recalled communication shall also advise consignees how to return the recall infant formula to the manufacturer or otherwise dispose of it. The recalling firm shall send a followup recall communication to any consignee that does not respond to the initial recall communication.

(d) If the infant formula presents a risk to human health, the recalling firm shall request that each establishment, at which such infant formula is sold or available for sale, post at the point of purchase of such formula a notice of such recall at such establishment. The notice shall be provided by the recalling firm after approval of the notice by the Food and Drug Administration. The recalling firm shall also request that each retail establishment maintain such notice on display until such time as the Food and Drug Administration notifies the recalling firm that the agency considers the recall completed.

(e) The recalling firm shall furnish promptly to the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter, as they are available, copies of the health hazard evaluation, the recall strategy, and all recall communications (including, for a recall under § 107.200, the notice to be displayed at retail establishments) directed to consignees, distributors, retailers, and members of the public.

§107.240 Notification requirements.

(a) *Notification of a violative infant formula.* A manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act)) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer:

(1) May not provide the nutrients required by section 412(i) of the act and

by regulations promulgated under section 412(i)(2) of the act; or

(2) May be otherwise adulterated or misbranded.

(b) *Method of notification.* The notification made pursuant to § 107.240(a) shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in § 5.115 of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), FDA's emergency number, 202–857–8400, shall be used. The manufacturer shall send written confirmation of the notification to the Division of Regulatory Guidance (HFF-310), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and to the appropriate Food and Drug Administration district office specified in § 5.115 of this chapter.

(c) *Reports about an infant formula recall*—(1) *Telephone report.* When a determination is made that an infant formula is to be recalled, the recalling firm shall telephone within 24 hours the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter and shall provide relevant information about the infant formula that is to be recalled.

(2) *Initial written report.* Within 14 days after the recall has begun, the recalling firm shall provide a written report to the appropriate Food and Drug Administration district office. The report shall contain relevant information, including the following cumulative information concerning the infant formula that is being recalled:

(i) Number of consignees notified of the recall, and date and method of notification, including, for a recall pursuant to § 107.200 information about the notice provided for retail display and the request for its display.

(ii) Number of consignees responding to the recall communication and quantity of recalled infant formula on hand at the time it was received.

(iii) Quantity of recalled infant formula returned or corrected by each consignee contacted and the quantity of recalled infant formula accounted for.

(iv) Number and results of effectiveness checks that were made.

(v) Estimated timeframes for completion of the recall.

(3) *Status reports.* The recalling firm shall submit to the appropriate Food and Drug Administration district office a written status report on the recall at least every 14 days until the recall is terminated. The status report shall describe the steps taken by the recalling firm to carry out the recall since the last report and the results of these steps.

§ 107.250 Termination of an infant formula recall.

The recalling firm may submit a recommendation for termination of the recall to the appropriate Food and Drug Administration district office listed in § 5.115 of this chapter for transmittal to the Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition, for action. Any such recommendation shall contain information supporting a conclusion that the recall strategy has been effective. The agency will respond within 15 days of receipt by the Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition, of the request for termination. The recalling firm shall continue to implement the recall strategy until it receives final written notification from the agency that the recall has been terminated. The agency will send such a notification unless it has information, from FDA's own audits or from other sources, demonstrating that the recall has not been effective. The agency may conclude that a recall has not been effective if:

(a) The recalling firm's distributors have failed to retrieve the recalled infant formula; or

(b) Stocks of the recalled infant formula remain in distribution channels that are not in direct control of the recalling firm.

§ 107.260 Revision of an infant formula recall.

If after a review of the recalling firm's recall strategy or periodic reports or other monitoring of the recall, the Food and Drug Administration concludes that the actions of the recalling firm are deficient, the agency shall notify the recalling firm of any serious deficiency. The agency may require the firm to:

(a) Change the extent of the recall, if the agency concludes on the basis of available data that the depth of the recall is not adequate in light of the risk to human health presented by the infant formula.

(b) Carry out additional effectiveness checks, if the agency's audits, or other information, demonstrate that the recall has not been effective.

(c) Issue additional notifications to the firm's direct accounts, if the agency's audits, or other information demonstrate that the original notifications were not received, or were disregarded in a significant number of cases.

§ 107.270 Compliance with this subpart.

A recalling firm may satisfy the requirements of this subpart by any means reasonable calculated to meet the obligations set forth in this Subpart E. The recall guidelines in Subpart C of Part 7 of this chapter specify procedures that may be useful to a recalling firm in determining how to comply with these regulations.

§ 107.280 Records retention.

Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least 1 year after the expiration of the shelf life of the infant formula.

(Collection of information requirements in this section were approved by the Office of Management and Budget under OMB control number 0910–0188.)

Dated: December 22, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 89–1719 Filed 1–26–89; 8:45 am]

BILLING CODE 4160–01

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[T.D. ATF–281; Ref: Notice Nos. 620, 644, 647]

Stags Leap District Viticultural Area

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This final rule establishes a viticultural area in Napa County, California, to be known as "Stags Leap District." The northern boundary alone has been modified from that originally proposed, to the Yountville Cross Road. The establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling and advertising will help consumers better identify the wines they may purchase, and will help winemakers distinguish their products from wines made in other areas.

EFFECTIVE DATE: February 27, 1989.

FOR FURTHER INFORMATION CONTACT: James P. Ficaretta, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, Ariel Rios Federal Building, 1200 Pennsylvania Avenue NW., Washington, DC 20226 (202–566–7626).