

Administration, 6401 Security Blvd.,
Baltimore, MD 21235, (301) 965-1753.

SUPPLEMENTARY INFORMATION: In these final regulations, we are making technical changes to correct cross-references and to replace erroneously deleted regulatory text. The rules relating to general eligibility for SSI benefits in subpart B of part 416 were revised and reorganized to make them clearer and easier to understand. These revisions were published as final rules on January 22, 1982, 47 FR 3099. As a result of this general reorganization, a number of cross-references to sections within subpart B appearing in other subparts of the SSI regulations became incorrect. All but two of those references have since been corrected. These final regulations correct those two remaining cross-references in subpart M at § 416.1321.

In addition, these final regulations correct the inadvertent removal of text from subpart T. The interim final rules reflecting sections 9113, 9114, and 9119 of Public Law 100-203, the Omnibus Budget Reconciliation Act of 1987, published on May 4, 1989, at 54 FR 19162, contained technically incorrect amendatory language for a section of the rules. The error in the amendatory language resulted in the inadvertent removal from the CFR of text relating to the basic pass along rules described in 20 CFR 416.2096. The amendments published on May 4, 1989, revised the then existing paragraph (a), the introductory text of (b), and (c), and added a new paragraph (d) to reflect the provisions of section 9119(b) of Public Law 100-203. The correct changes were made to these paragraphs and paragraph (d) was added to the regulations. However, the erroneous amendatory language resulted in the inadvertent removal of the text contained in paragraphs (a)(1) (i), (ii), and (iii) and (a)(2). These final regulations return those paragraphs to the regulations.

Justification for Final Rules

The Department generally follows the notice of proposed rulemaking and public comment procedures specified in the Administrative Procedure Act (APA); 5 U.S.C. 553, in the development of its regulations. The APA provides exceptions to its notice and public comment procedures when an agency finds that there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that,

under 5 U.S.C. 553(b)(3)(B), good cause exists for waiver of notice of proposed rulemaking and public comment procedures with respect to these regulations. Opportunity for public comment is unnecessary since these regulations merely correct two erroneous cross-references and return to the regulations material that was inadvertently removed. These changes are technical and do not involve the setting of policy. Therefore, the use of notice and comment rulemaking is unnecessary and these regulations are being issued as final rules.

Regulatory Procedures

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291 because these regulations make no substantive changes and merely correct erroneous cross-references and return to the regulations inadvertently removed material. They therefore do not meet any of the threshold criteria for a major rule and a regulatory impact analysis is not required.

Paperwork Reduction Act

These regulations impose no additional reporting and recordkeeping requirements necessitating clearance by the Office of Management and Budget.

Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only individuals and States. Therefore, a regulatory flexibility analysis as provided in Public Law 96-354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Program No. 93.807, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income.

Dated: August 5, 1991.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: September 12, 1991.

Louis W. Sullivan,

Secretary of Health and Human Services.

Part 416 of chapter III of title 20 of the Code of Federal Regulations is amended to read as follows:

1. The authority citation for subpart M is revised to read as follows:

Authority: Secs. 1102, 1611-1615, 1619 and 1631 of the Social Security Act; 42 U.S.C. 1302, 1382-1382d, 1382h, 1383.

2. Section 416.1321 is amended by revising the references in paragraph (c)(1) from § 416.230(c) and § 416.230(d) to § 416.210(c) and § 416.210(e)(2) respectively.

3. The authority citation for subpart T is revised to read as follows:

Authority: Secs. 1102, 1616, 1618, and 1631 of the Social Security Act; 42 U.S.C. 1302, 1382e, 1382g, and 1383; Sec. 212 of Pub. L. 93-66, 87 Stat. 155; sec. 8 of Pub. L. 93-233, 87 Stat. 956; secs. 1 and 2 of Pub. L. 93-335, 88 Stat. 291.

4. Section 416.2096 is amended by adding paragraphs (a)(1) (i), (ii), (iii) and (2) to read as follows:

§ 416.2096 Basic passalong rules.

(a) *State agreements to maintain supplementary payment levels.* (1) * * *

(i) The State must agree to continue to make the supplementary payments;

(ii) For months from July 1977 through March 1983, the State must agree to maintain the supplementary payments at levels at least equal to the December 1976 levels (or, if a State first makes supplementary payments after December 1976, the levels for the first month the State makes supplementary payments). For months in the period July 1, 1982 through March 31, 1983, a State may elect to maintain the levels described in paragraph (b)(2) of this section; and

(iii) For months after March 1983, the State must agree to maintain supplementary payments at least sufficient to maintain the combined supplementary/SSI payment levels in effect in March 1983, increased by any subsequent SSI benefit increases, except as provided in § 416.2097(b) and § 416.2097(c).

(2) We will find that the State has met the requirements of paragraph (a)(1) of this section if the State has the appropriate agreement in effect and complies with the conditions in either paragraph (b) or (c) of this section. We will consider a State to have made supplementary payments on or after June 30, 1977, unless the State furnishes us satisfactory evidence to the contrary.

[FR Doc. 91-25853 Filed 10-25-91; 8:45 am]

BILLING CODE 4190-29-M

Food and Drug Administration**21 CFR Part 5****Delegations of Authority and Organization; Center for Drug Evaluation and Research**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to approval of new drug applications and their supplements. The amendment delegates authority to the director, Division of Oncology and Pulmonary Drug Products, Center for Drug Evaluation and Research (CDER), to approve new drug applications (NDA's) and their supplements for oncologic drug products.

EFFECTIVE DATE: October 28, 1991.

FOR FURTHER INFORMATION CONTACT: Ellen Rawlings, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: FDA is amending § 5.80 *Approval of new drug applications and their supplements* (21 CFR 5.80) to redelegate authority to the Director, Division of Oncology and Pulmonary Drug Products, CDER, to approve NDA's and their supplements for oncologic drug products. This amendment adds new paragraph (a)(1)(iv) to § 5.80.

Further redelegation of the authority delegated is not authorized.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organizations and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50; 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354-360f, 361, 362, 1701-1706, 2101-2672 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b-263n

264, 265, 300u-300u-5, 300aa-1-300ff); 42 U.S.C. 1395h, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591.

2. Section 5.80 is amended by adding new paragraph (a)(1)(iv) to read as follows:

§ 5.80 Approval of new drug applications and their supplements.

(a) (1) * * *

(iv) The director, Division of Oncology and Pulmonary Drug Products, CDER, for oncologic drug products. This authority may not be redelegated.

* * *

Dated: October 21, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-25896 Filed 10-25-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 178

[Docket No. 89F-0215]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of α -butyl- Ω -hydroxypoly (oxypropylene), minimum molecular weight 1000, as a surface lubricant in the manufacture of metallic articles that contact food. This action is in response to a petition filed by Union Carbide Corp.

DATES: Effective October 28, 1991; written objections and requests for a hearing by November 27, 1991.

ADDRESSES: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sandra L. Varner, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street, SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of August 7, 1989 (54 FR 32395), FDA announced that a food additive petition (FAP 9B4151) had been filed by Union Carbide Corp., Old Saw Mill River Rd., Tarrytown, NY 10591, proposing that § 178.3910 *Surface lubricants used in the manufacture of metallic articles* (21 CFR 178.3910) be amended to provide for the safe use of α -butyl- Ω -hydroxypoly (oxypropylene), minimum molecular

weight 1000, as a surface lubricant in the manufacture of metallic articles that contact food.

FDA, in its evaluation of the safety of this additive, reviewed the safety of both the additive and the starting materials used to manufacture the additive. This additive has not been found to cause cancer. However, propylene oxide, which could be present as an impurity in the additive, has been shown to cause cancer in test animals. Residual amounts of reactants and byproducts, such as propylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d Sess. 4 (1958).) This definition of safety has been incorporated into FDA's food additive regulations (§ 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A) of the act) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain carcinogenic impurities but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the *Federal Register* of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though the additive contains a carcinogenic

impurity. Since that decision, FDA has approved the use of other color additives and food additives on the same basis. An additive that has not been shown to cause cancer, but that contains a carcinogenic impurity, may properly be evaluated under the general safety clause of the statute, using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive.

The agency's position is supported by *Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to list D&C Green No. 5, which contains a carcinogenic impurity but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the U.S. Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use

FDA estimates that the petitioned use of α -butyl- Ω -hydroxypoly (oxypropylene), minimum molecular weight 1000, will result in extremely low levels of exposure to this additive. The agency calculated the estimated daily intake of the additive based on several worst-case assumptions: (1) That the total residual lubricant remaining on the metallic food-contact article was at the regulatory limit (0.015 milligrams per square inch); (2) that the lubricant contained the maximum use level of the additive or 20 percent; and (3) that all of the additive migrates into the food in contact with the metallic article. Based upon these assumptions and assuming that each square inch of the metallic food-contact article contacts 10 grams of food, the agency estimates the daily intake for the additive will not exceed 30 micrograms per person per day or 10 parts per billion in the diet.

FDA does not ordinarily consider chronic testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Refs. 1 and 2), and the agency has not required such testing here. However, the agency has reviewed available data from acute oral toxicity studies of the additive in rats and from subchronic and chronic feeding studies of the additive in rats and dogs. Based on the results of these studies and the low level of exposure to the additive, the agency concludes that there is an adequate margin of safety for the proposed use of the additive.

A. The Impurity, Propylene Oxide

Because the additive itself has not been shown to cause cancer, the

anticancer clause does not apply. However, FDA has further evaluated the safety of the additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by the carcinogenic chemical propylene oxide that may be present as an impurity in the additive.

The risk assessment procedures that FDA used in its evaluation are similar to the methods that the agency has used to examine the risk associated with the presence of minor carcinogenic impurities in various other food or color additives that contain carcinogenic impurities (e.g., 49 FR 13018 at 13019; April 2, 1984). The risk evaluation of the carcinogenic impurity propylene oxide has two aspects: (1) Assessment of the worst-case exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

Based on the fraction of the daily diet that may be in contact with surfaces containing the additive and the level of propylene oxide that may be present in the additive, FDA estimates that the hypothetical worst-case exposure to propylene oxide from the petitioned use of the additive will be 0.3 nanograms (ng) per person per day or 0.1 parts per trillion in the daily diet (Ref. 3). The agency used data from a carcinogenesis bioassay on propylene oxide conducted by the Institute of Hygiene, University of Mainz, Germany (Ref. 4), to estimate the upper-bound level of lifetime human risk from exposure to propylene oxide resulting from the proposed use of the additive. The results of the bioassay on propylene oxide demonstrated that the material was carcinogenic for female rats under the conditions of the study, causing carcinomas and papillomas in the squamous epithelium of the forestomach.

The Quantitative Risk Assessment Committee (the committee) of the Center for Food Safety and Applied Nutrition reviewed this bioassay and other relevant data available in the literature and concluded that the findings of carcinogenicity were supported by this information on propylene oxide. The committee further concluded that the bioassay provided an appropriate basis on which to calculate an estimate of the upper-bound level of lifetime human cancer risk from potential exposure to propylene oxide stemming from the proposed use of α -butyl- Ω -hydroxypoly (oxypropylene), minimum molecular weight 1000 (Refs. 5, 6, and 7)

The committee used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose used in the animal experiments to the very low doses encountered under the proposed conditions of use. This procedure is not likely to underestimate the actual risk from very low doses and may, in fact, exaggerate it because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the proposed conditions and levels of use of the additive.

Based on a worst-case exposure to propylene oxide of 0.3 ng per person per day, FDA estimates that the upper-bound limit of individual lifetime risk from the potential exposure to propylene oxide from the use of α -butyl- Ω -hydroxypoly (oxypropylene), minimum molecular weight 1000, is 2.1×10^{-10} , or less than 1 in 4.8 billion (Ref. 7). Because of the numerous conservatism in the exposure estimate, lifetime-averaged individual exposure to propylene oxide is expected to be substantially less than the estimated daily intake, and therefore, the calculated upper-bound risk would be less. Thus, the agency concludes that there is a reasonable certainty of no harm from exposure to propylene oxide that might result from the proposed use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of propylene oxide in the food additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which propylene oxide may be expected to remain as an impurity following production of the additive, the agency would not expect this impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime risk from exposure to this impurity, even under worst-case assumptions, is very low (less than 1 in 4.8 billion).

III. Conclusion of Safety

FDA has evaluated the data in the petition and other relevant material, including the information pertaining to the safety of the potential impurity, propylene oxide. The agency concludes that the proposed use of the food additive is safe and that 21 CFR 178.3910(a)(2) should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents

that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before November 27, 1991 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons

between 9 a.m. and 4 p.m., Monday through Friday.

1. Carr, G. M., "Carcinogenicity Testing Programs" in *Food Safety: Where Are We?*, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, p. 59, July 1979.
2. Kokoski, C. J., "Regulatory Food Additive Toxicology" in *Chemical Safety Regulation and Compliance*, F. Homburger and J. K. Marquis, Eds., New York, pp. 24-33, 1985.
3. Memorandum dated June 28, 1989, from Food and Color Additives Review Section to Indirect Additives Branch, "FAP 9B4151—Union Carbide Corp. (UC). Alpha-butyl-omega-hydroxy-poly (oxypropylene) as a component of surface lubricants used in the manufacture of metal foils. Submission of 5-12-89."
4. Dunkelberg, H., "Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide Upon Intragastric Administration to Rats," in *British Journal of Cancer*, 46:924, 1982.
5. Report of the Quantitative Risk Assessment Committee, dated August 29, 1990, "Estimation of Upper Bound Risk for Propylene Oxide in a Surface Lubricant Used in the Manufacture of Metal Foils in FAP 9B4151 (Union Carbide Corp.)."
6. Memorandum dated May 30, 1991, from Food and Color Additives Review Section to Indirect Additives Branch, "FAP 9B4151—Union Carbide Corp. (UC). Alpha-butyl-omega-hydroxy-poly(oxypropylene) as a component of surface lubricants used in the manufacture of metal foils. 'Typical' versus 'worst-case' exposure. DFCA request of 1-31-91."
7. Report of the Quantitative Risk Assessment Committee, dated August 1, 1991, "Revision: Estimation of Upper Bound Lifetime Risk for Propylene Oxide in a Surface Lubricant Used in the Manufacture of Metal Foils in FAP 9B4151 (Union Carbide Corp.)."

List of Subjects in 21 CFR Part 178

Food additives, Food packaging. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR Part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.3910 is amended in paragraph (a)(2) by alphabetically adding a new entry to the table to read as follows:

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

- | |
|-----------|
| * * * |
| (a) * * * |
| (2) * * * |

List of substances	Limitations
α-Butyl-Ω-hydroxypoly(oxypropylene) (CAS Reg. No. 9003-13-8) having minimum molecular weight of 1000	For use at levels not to exceed 20 percent by weight of the finished lubricant formulation.

Dated: October 21, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-25844 Filed 10-25-91; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF STATE

Office of the Legal Adviser

22 CFR Part 7

[Public Notice 1505]

Loss of United States Nationality

In the matter of Regulations Pertaining to Administrative Reconsideration by the Department of State of its Decisions Concerning Loss of Nationality Under Chapters 3 and 4 of the Immigration and Nationality Act of 1952, as amended, 8 U.S.C. 1101 *et seq.*

AGENCY: Office of the Legal Adviser, DOS.

ACTION: Final rule.

SUMMARY: This rule amends 22 CFR 7.2(b) and 7.9 to remove a potential ambiguity by expressly providing that the Department of State ("Department") may administratively vacate a Certificate of Loss of Nationality ("CLN"), notwithstanding that the Board of Appellate Review ("Board") may have issued an intervening decision sustaining the Department's original action.

EFFECTIVE DATE: October 28, 1991.

FOR FURTHER INFORMATION CONTACT: Jamison M. Selby, Deputy Legal Adviser, Department of State, 202-647-7942.

SUPPLEMENTARY INFORMATION: Section 349(a) of the Immigration and Nationality Act of 1952, as amended, 8 U.S.C. 1101 *et seq.* ("INA"), specifies the circumstances under which nationals of the United States may lose their U.S. nationality. See *Vance v. Terrazas*, 444 U.S. 252 (1980). Under section 358 of the INA, 8 U.S.C. 1501, diplomatic and consular officers of the United States are required to certify to the Department cases in which they have reason to believe that persons have lost their U.S. nationality under any of the provisions of Chapter 3 of the INA. If the

Department approves the certification, it issues a CLN.

Individuals who wish to challenge the Department's decision to issue a CLN may file an administrative appeal with the Board, pursuant to 22 CFR part 7. 22 CFR 7.2(b) provides, in relevant part, that "[t]he merits of appeals or decisions of the Board shall not be subject to review by the Legal Adviser or any other Department official." 22 CFR 7.9 provides, in relevant part, that "decision(s) of the Board shall be final."

Recently, a question arose concerning the proper interpretation of these provisions when the Department administratively vacated several CLNs in cases in which the Board had issued intervening decisions sustaining the Department's actions in issuing the CLNs. Although the Legal Adviser issued an opinion on 29 May 1991 sustaining the Department's authority to effect such administrative redeterminations, the Department considers that it would be advisable to avoid any possible confusion on this point by amending 22 CFR part 7.

This final rule amends 22 CFR 7.2(b) by adding the following sentence: "Nothing in these regulations, however, shall be deemed to preclude the Department from administratively vacating Certificates of Loss of Nationality on its own initiative at any time, notwithstanding an intervening decision by the Board sustaining the Department's original determination". The final rule makes a corresponding change to 22 CFR 7.9 by amending the third sentence thereof to read as follows: "The decision of the Board shall be final, subject to §§ 7.2(b) and 7.10"

The provisions of 5 U.S.C. 553 relative to notice of final rule and delayed effective date are not required in this rule because the changes herein relate solely to internal agency management matters. This rule is not considered to be a major rule for purposes of E.O. 12291 nor will it have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act.

List of Subjects in 22 CFR Part 7

Administrative practice and procedure, citizenship and naturalization, organization and functions (Government agencies).

Accordingly, part 7 to title 22, Code of Federal Regulations, is amended as indicated below.

PART 7—[AMENDED]

1. Section 7.2, paragraph (b) is revised to read:

§ 7.2 Establishment of Board of Appellate Review; purpose.

(b) For administrative purposes, the Board shall be part of the Office of the Legal Adviser. The merits of appeals or decisions of the Board shall not be subject to review by the Legal Adviser or any other Department official, except that the Department may administratively vacate a Certificate of Loss of Nationality on its own initiative at any time, notwithstanding an intervening decision by the Board sustaining the Department's original determination.

2. Section 7.9 is revised to read:

§ 7.9 Decisions.

The Board shall decide the appeal on the basis of the record of the proceedings. The decision shall be by majority vote in writing and shall include findings of fact and conclusions of law on which it is based. The decision of the Board shall be final, subject to §§ 7.2(b) and 7.10. Copies of the Board's decision shall be forwarded promptly to the parties.

Dated: October 4, 1991.

Edwin D. Williamson,
Legal Adviser.

[FR Doc. 91-25581 Filed 10-25-91; 8:45 am]

BILLING CODE 4710-08-M

Bureau of Politico-Military Affairs

22 CFR Parts 120, 123, and 126

[Public Notice 1509]

Amendments to the International Traffic in Arms Regulations (ITAR)

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule, arrived at through coordination with industry and U.S. Government agencies (e.g., Department of Defense), and consultation with industry through the 30 day public review process, clarifies and amends the regulations implementing section 38 of the Arms Export Control Act, which governs the export of defense articles and defense services. Specifically, it makes explicit certain limits on the definition of technical data; expands an existing exemption from licensing requirements for shipments by or for U.S. Government agencies; and creates a new exemption for specialized packing cases for defense articles. This rule is intended to reduce the burden on munitions exporters: It clarifies when a license is needed to export technical data and eliminates the need for prior

U.S. Government approval for certain transactions.

EFFECTIVE DATE: October 28, 1991.

FOR FURTHER INFORMATION CONTACT: Rose Biancaniello, Chief, Arms Licensing Division, Office of Defense Trade Controls, Department of State, (703-875-6644).

SUPPLEMENTARY INFORMATION: This rule amends the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120-130), which implements section 38 of the Arms Export Control Act (22 U.S.C. 2778). This amendment clarifies when a license is needed to export technical data and eliminates licensing requirements for certain exports of defense articles. It is one of a series of ITAR changes intended to eliminate requirements on munitions exporters that are no longer necessary.

First, this amendment revises the definition of technical data for purposes of the ITAR by making explicit that it does not include basic marketing information on function or purpose, or general system descriptions of defense articles.

Second, this amendment adds packing cases specially designed to carry defense articles to the list of those items covered by the U.S. Munitions List that are exempt from the licensing requirements of the ITAR.

Third, these changes relax the requirements that must be met before exporting defense articles for U.S. Government use abroad without an export license or a U.S. Bill of Lading.

Specifically, it removes the requirements that exporters certify that the urgency of the U.S. Government need is such that an appropriate export license or U.S. Government Bill of Lading could not be obtained in a timely manner. In addition, this amendment makes clear that the exporter certification required whenever this exemption is used must be submitted to the Office of Defense Trade Controls at the same time as the shipper's export declaration required under § 123.25(c).

This rule affects collection of information subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), and will serve to reduce the burden on exporters in that respect. The relevant information collection is to be reviewed by the Office of Management and Budget under control No. 1405-0013.

Accordingly, for the reasons set forth in the preamble, title 22 chapter I, subchapter M (consisting of parts 120 through 130) of the Code of Federal Regulations, is amended as set forth below: