

FDA did not receive comments that would affect the Paperwork Reduction Act burden estimates made in the 2011 IFR (76 FR 25542 at 25544). Therefore the estimated Paperwork Reduction Act burden for this final rule is the same as the estimated burden in the 2011 IFR.

VII. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ Accordingly, the interim rule amending 21 CFR part 1, which was published at 76 FR 25542 on May 5, 2011, is adopted as a final rule without change.

Dated: May 22, 2013.

Kathleen Sebelius,

Secretary of Health and Human Services.

Dated: May 22, 2013.

Janet Napolitano,

Secretary of Homeland Security.

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DEPARTMENT OF STATE

22 CFR Parts 120 and 126

RIN 1400–AD38

[Public Notice 8335]

Implementation of the Defense Trade Cooperation Treaty Between the United States and Australia; Announcement of Effective Date for Regulations

ACTION: Final rule; announcement of effective date.

SUMMARY: This rule provides an effective date for previously published regulations implementing the Treaty Between the Government of the United States of America and the Government of Australia Concerning Defense Trade Cooperation (referred to herein as “the Treaty”).

DATES: *Effective Date:* The rule, “Implementation of the Defense Trade Cooperation Treaty Between the United States and Australia,” published on April 11, 2013 (Public Notice 8270, 78 FR 21523) is effective May 16, 2013.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: The rule (Public Notice 8270, 78 FR 21523), published on April 11, 2013, amends the International Traffic in Arms Regulations to implement the Treaty, and identifies via a supplement the defense articles and defense services that may not be exported pursuant to the Treaty. The Department of State indicated in the rule that it would become effective upon the entry into force of the Treaty, and that the Department of State would publish another rule announcing its effective date. The Treaty entered into force on May 16, 2013. Therefore, the rule is in effect as of that date. The Department’s regulatory analyses with respect to this Rule were published at 78 FR 21523, and are hereby incorporated by reference.

Dated: May 20, 2013.

Rose E. Gottemoeller,

Acting Under Secretary, Arms Control and International Security, Department of State.

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