approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we do not believe any companies are currently selling or producing these devices, the agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. How Does the Paperwork Reduction Act of 1995 Apply to This Proposed Rule?

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. What Are the Federalism Impacts of This Proposed Rule?

FDA has analyzed this proposed 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.

IX. How Do You Submit Comments on This Proposed Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, and Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed to amend 21 CFR part 866 as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 866.3305 is amended by removing paragraph (c) and by revising paragraph (b) to read as follows:

§ 866.3305 Herpes simplex virus serological assays.

* * * * *

(b) *Classification.* Class II (special controls). The device is classified as class II (special controls). The special control for the device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays.'' For availability of the guidance document, see § 866.1(e).

Dated: August 17, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–20415 Filed 8–24–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 40, 41, 44, and 45

[Docket No. TTB–2009–0002; Notice No. 98; Re: Notice No. 95, T.D. TTB–78 and T.D. TTB–80]

RIN 1513–AB72

Implementation of Statutory Amendments Requiring the Qualification of Manufacturers and Importers of Processed Tobacco and Other Amendments Related To Permit Requirements, and the Expanded Definition of Roll-Your-Own Tobacco; Extension of Comment Period

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking; reopening of comment period.

SUMMARY: In response to a request filed on behalf of several industry members, the Alcohol and Tobacco Tax and Trade Bureau is reopening the comment period for Notice No. 95, a notice of proposed rulemaking published in the **Federal Register** on June 22, 2009. The proposed rule seeks comments on a concurrently published temporary rule implementing permit requirements for manufacturers and importers of processed tobacco and an expansion of the definition of roll-your-own tobacco adopted in the Children's Health Insurance Program Reauthorization Act of 2009. The text of the regulations contained in the temporary rule serves as the text of the proposed regulations.

DATES: The comment period for the proposed rule (Notice No. 95) published June 22, 2009, at 74 FR 29433 is reopened. Written comments on Notice No. 95 must now be received on or before October 20, 2009.

ADDRESSES: You may send comments on Notice No. 95 to one of the following addresses:

- *http://www.regulations.gov* (via the online comment form for Notice No. 95 as posted within Docket No. TTB–2009–0002 at ''Regulations.gov,'' the Federal e-rulemaking portal);
- Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044–4412; or
- *Hand Delivery/Courier in Lieu of Mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200–E, Washington, DC 20005.

See the Public Participation section of Notice No. 95 for specific instructions and requirements for submitting

comments, and for information on how to request a public hearing.

You may view copies of this notice, Notice No. 95, any comments received, the related temporary rule (T.D. TTB–78), and a correction to the temporary rule (T.D. TTB–80) at *http://www.regulations.gov.* A direct link to the related Regulations.gov docket also is available under Notice No. 95 on the TTB Web site at *http://www.ttb.gov/regulations_laws/all_rulemaking.shtml.* You also may view copies of these documents by appointment at the TTB Information Resource Center, 1310 G Street, NW., Washington, DC 20220. To make an appointment, call 202–453–2270 (new phone number).

FOR FURTHER INFORMATION CONTACT: For questions concerning processed tobacco permit and authorization procedures, contact the National Revenue Center, Alcohol and Tobacco Tax and Trade Bureau at 1–877–882–3277; for other questions concerning this document, Notice No. 95, or the related temporary rule, contact Amy Greenberg, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau at 202–453–2099 (new phone number).

SUPPLEMENTARY INFORMATION: In the **Federal Register** issue of June 22, 2009, the Alcohol and Tobacco Tax and Trade Bureau (TTB) published a temporary rule (T.D. TTB–78; 74 FR 29401) setting forth regulatory amendments to 27 CFR parts 40, 41, 44, and 45 to implement certain changes made to the Internal Revenue Code of 1986 by the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3, 123 Stat. 8). The principal changes made by CHIPRA involve permit and related requirements for manufacturers and importers of processed tobacco and an expansion of the definition of roll-your-own tobacco.

In the same issue of the **Federal Register**, we concurrently published a notice of proposed rulemaking, Notice No. 95 (74 FR 29433), to request comments on the regulatory amendments contained in the temporary rule. The preamble to the temporary regulations explained the proposed regulations. As originally published, comments on Notice No. 95 were due on August 21, 2009. (On July 29, 2009, we published corrections to the temporary rule in T.D. TTB–80 at 74 FR 37551.)

On August 19, 2009, TTB received a letter from a law firm representing the John Middleton Co., Philip Morris USA Inc., and U.S. Smokeless Tobacco Manufacturing Co. LLC, requesting an extension of the comment period for Notice No. 95. In the letter, the requester noted the temporary rule's immediate effective date and the fact that TTB issued the temporary rule and the related notice of proposed rulemaking just before the annual TTB Expo, which was attended by many company officials. The letter stated these events gave the companies ''little time to digest the implications of the temporary rule prior to the Expo * * *.'' Since returning from the Expo, the companies have found ''the process of identifying all activity within the factories that might have implications for processed tobacco'' to be ''extensive and time consuming.''

The letter also noted that the TTB temporary rule was issued on the same day as the enactment of the Family Smoking Prevention and Tobacco Control Act, which provides for regulation of tobacco products by the Food and Drug Administration. ''Thus,'' the letter states, ''key personnel within the Companies and other industry entities were involved in evaluation of this legislation and identification of its implications for their operations.'' The letter additionally noted that the comment period on the proposed rule coincided with the summer vacation season when company officials are most likely to be away from their offices.

Given the factors cited above, TTB agrees that the comment period for Notice No. 95 should be extended by an additional 60 days. Therefore, comments on Notice No. 95 are now due on October 20, 2009.

Drafting Information

Michael Hoover of the Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, drafted this document.

Signed: August 20, 2009.

Cheri D. Mitchell,

Acting Administrator.

[FR Doc. E9–20404 Filed 8–24–09; 8:45 am]

BILLING CODE 4810–31–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2009–0462, FRL–8949–1]

Approval and Promulgation of Implementation Plans; New York Reasonably Available Control Technology and Reasonably Available Control Measures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing action on portions of a State Implementation Plan revision submitted by New York State that are intended to meet some Clean Air Act requirements for attaining the 0.08 parts per million 8-hour ozone national ambient air quality standards. EPA is proposing to disapprove the reasonably available control technology requirement as it relates to the entire State of New York, including the New York portion of the New York-Northern New Jersey-Long Island, NY–NJ–CT and the Poughkeepsie 8-hour ozone moderate nonattainment areas.

In addition, EPA is proposing to disapprove the reasonably available control measure analysis as it relates to the New York portion of the New York-Northern New Jersey-Long Island, NY–NJ–CT 8-hour ozone moderate nonattainment area.

DATES: Comments must be received on or before September 24, 2009.

ADDRESSES: Submit your comments, identified by Docket Number EPA–R02–OAR–2009–0462, by one of the following methods:

- *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.
- *E-mail: Werner.Raymond@epa.gov*.
- *Fax:* 212–637–3901.
- *Mail:* Raymond Werner, Chief, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866.
- *Hand Delivery:* Raymond Werner, Chief, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30 excluding Federal holidays.

Instructions: Direct your comments to Docket No. EPA–R02–OAR–2009–0462. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which