DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

April 16, 2013

Dear Colleague:

Federalism Outreach

This communication is part of our outreach to state and local officials in response to the Presidential Executive Order 13132, "Federalism." In accordance with federalism principles, we want to provide you with the opportunity for meaningful and timely input in the development of regulatory policies that have substantial direct effects: (1) on the states; (2) on the relationship between the national government and the states; or (3) on the distribution of power and responsibilities among the various levels of government.

The Food and Drug Administration (FDA) has adopted this process to enhance state and local government's input by sending state and local officials and their organizations notice of the publication of the *Regulatory Plan and Unified Agenda of Federal Regulations (Agenda)*. With this notice and the information we provide on locating the *Plan* and *Agenda* on the Internet, we send a list of those regulatory items that we think will be of particular interest to state and local governments.

Information for You on the Unified Agenda of Federal Regulations

The *Plan* and *Agenda* provide, among other things, abstracts of all proposed and final regulations currently planned by FDA for the next six to twelve months, as well as abstracts of planned long-term actions and completed actions. Each entry also contains an indication as to what government level may be affected, e.g., state or local. The *Plan and Agenda* is published in the Federal Register twice a year (usually in April and October), with the fall edition also containing the *Regulatory Plan*. Below is a listing of 22 rulemakings on the *Agenda* that we identified that will impact state or local governments. We encourage you to review these abstracts and to provide any comments or raise any questions you may have to the contact person listed, Barbara Cassens, Senior Advisor of FDA's Office of Partnerships at (510) 590-3002 (email: Barbara.Cassens@fda.hhs.gov) or me.

The *Plan* and *Agenda* for the Food and Drug Administration for Fall 2012 published in the Federal Register on January 8, 2013 (78 FR 1574). However, the version printed in the Federal Register only contains selected rulemakings, and does not contain information on Federalism. The complete *Plan* and *Agenda* is only available online at Regulations.gov. Please note that the rulemakings are identified by the Regulatory Information Number (RIN).

They can be found on the internet at the following location:

a) Go to Internet site Regulations.gov
b) Scroll down to "Resources," and click on "Regulatory Agenda." (You will be re-directed; click "ok".)
c) Make sure that at "Select Publication Date" that "Fall 2012" is displayed.
d) Under "Select Agency," scroll down to "Department of Health and Human Services," and click "Go."
e) Scroll through to see FDA's portion and to see a specific entry, click on the RIN in blue.

Suggestions Are Welcome

We welcome suggestions and other comments from you and others at the state and local government level on FDA's activities to enhance your input in the development of FDA's regulations, especially those regulations that have a substantial and direct effect on you. Again, you may send your comments and suggestions to the contact person listed for a particular Federal Register document, or by contacting Barbara Cassens of the FDA's Office of Partnerships or me.

Sincerely,

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Enclosures: List of 16 Rulemakings Identified by FDA with Impact on State or Local Governments in the Unified Agenda, and List of 6 Rulemakings Identified by FDA with Undetermined Impact on State or Local Governments, all of which can be found in the *Regulatory Plan and Unified Agenda* which is available at Regulations.gov and published in the Federal Register on January 8, 2013.

FDA IDENTIFIED RULEMAKINGS WITH IMPACT
ON STATE OR LOCAL GOVERNMENTS*

1. "Over-the-Counter (OTC) Drug Review– Sunscreen Products," RIN 0910-AF43

2. "Food Labeling; Revision of Nutrition and Supplemental Facts Labels," RIN 0910-AF22

3. "Food Labeling; Serving Sizes of Foods that can Reasonably be Consumed in One Eating Occasion; Dual Column Labeling; and Modifying the Reference Amounts Customarily Consumed," RIN 0910-AF23

4. "OTC Drug Review—Cough/Cold (Antihistamine) Products," RIN 0910-AF-31

5. "OTC Drug Review–Internal Analgesic Products," RIN 0910-AF36

6. "OTC Drug Review–Topical Antimicrobial Drug Products," RIN 0910-AF69

7. "Laser Products; Amendment to Performance Standards," RIN 0910-AF87

8. "OTC Drug Review--Pediatric Dosing for Cough/Cold Products," RIN 0910-AG12

9. "General Infusion and Personal Use Devices: Issuance of Draft Special Controls Guidance for Infusion Pumps," RIN 0910-AG54

10. "Food Labeling; Hard Candies and Breath Mints," RIN 0910-AG82

11. "Food Labeling; Serving Sizes; Reference Amounts for Candies," RIN 0910-AG83

12. "OTC Drug Review—Cough/Cold (Combination) Products," RIN 0910-AF33

13. "Current Good Manufacturing Practice for Combination Products," RIN 0910-AF81

14. "Food Labeling: Nutrition Labeling for Food Sold in Vending Machines," RIN 0910-AG56 (Regulatory Plan)

15. "Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments," RIN 0910-AG57 (Regulatory Plan)

16. “Food Labeling; Gluten-Free Labeling of Foods,” RIN 0910-AG84

FDA IDENTIFIED RULEMAKINGS WITH UNDETERMINED IMPACT ON STATE OR LOCAL GOVERNMENTS

1. “Produce Safety Regulation,” RIN 0910-AG35 (Regulatory Plan)

2. “Hazard Analysis and Risk-Based Preventive Controls,” RIN 0910-AG36 (Regulatory Plan)

3. “’Tobacco Products’ Subject to the Federal Food, Drug, and Cosmetic Act as Amended by the Family Smoking Prevention and Tobacco Control Act,” RIN 0910-AG38

4. “Food Labeling; Dietary Guidance Statement,” RIN 0910-AG50

5. “Requirements for Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives,” RIN 0910-AF59

6. “Accreditation of Third Parties to Conduct Food Safety Audits and for Other Related Purposes,” RIN 0910-AG66 (Regulatory Plan)

7. “Postmarketing Safety Reporting for Combination Products,” RIN 0910-AF82

*Abstracts of these planned rulemakings appear in the *Regulatory Plan and Unified Agenda of Federal Regulations*. The *Plan* and *Agenda* were published in the Federal Register on January 8, 2013. It may be found on the Internet (see letter for instructions).