DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville, Maryland 20857

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 online at Regulations.gov and in the Federal Register twice a year (usually in the Spring and Fall), with the Fall edition also containing the *Regulatory Plan*. Below is a listing of 40 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, Nicholas Alexander, Director of FDA's Intergovernmental Affairs, Office of Policy, Planning, Legislation, and Analysis at 301-796-8893, or me.

The *Agenda* for the Food and Drug Administration for Fall 2017 was made available online on December 14, 2017, at Regulations.gov and published in the Federal Register on January 12, 2018 (83 FR 1664). However, the version printed in the Federal Register only contains selected rulemakings, and does not contain information on Federalism. The complete *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 2017” 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 Brian Kehoe, Director of the FDA’s Intergovernmental Affairs, or me.

Sincerely,

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Enclosures: List of 17 Rulemakings Identified by FDA with Impact on State or Local Governments in the Unified Agenda, and List of 23 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 on December 14, 2017 and published in the Federal Register on January 12, 2018. (see instructions above)

FDA IDENTIFIED RULEMAKINGS WITH IMPACT
ON STATE OR LOCAL GOVERNMENTS

1. "Over-the-Counter (OTC) Drug Review– Cough/Cold (Antihistamine) Products," RIN 0910AF-31

2. "Mammography Quality Standards Act; Regulatory Amendments," RIN 0910-AH04

3. "General and Plastic Surgery Devices; Sunlamps," RIN 0910-AH14

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

5. "Combinations of Bronchodilators With Nasal Decongestant; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use," RIN 0910-AF33

6. "OTC --Drug Review External Analgesic Products," RIN 0910-AF35

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

8. "Sunscreen Drug Products For Over-The-Counter-Human Use; Tentative Final Monograph," RIN 0910-AF43

9. "Over-the-Counter (OTC) Drug Review--Pediatric Dosing for Cough/Cold Products," RIN 0910-AG12

10. "Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, Neutral Manner," RIN 0910-AG27

11. "Combinations of Bronchodilators With Expectorants; Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use," RIN 0910-AH16

12. "Safety and Effectiveness of Healthcare Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use," RIN 0910-AH40

13. "Postmarketing Safety Reports for Approved New Animal Drugs; Electronic Submission Requirements," RIN 0910-AH51

14. "Post Approval Changes to Approved Applications," RIN 0910-AH55

15. "Radiological Health; Amendments to Records and Report," RIN 0910-AH65

16. “Medical Devices; Amendments to Medical Software Regulations,” RIN 0910-AH67

17. Food Labeling: Revision of the Nutrition and Supplement Facts Labels and Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and E,” RIN 0910-AH92

1. “Sunlamp Products; Proposed Amendment to the Performance Standard,” RIN 0910-AG30

2. “National Standards for Licensing of Prescription Drug Wholesale Distributor and Third-Party Logistic Providers,” RIN 0910-AH11

3. “Medical Devices; Internal Agency Review of Decision; Requests for Review of Medical Device Decisions RIN 910-AH37

4. “Food Standards: General Principles and Food Standards Modernization,” RIN 0910-AC54

5. “Over-the-Counter (OTC) Drug Review--Laxative Drug,” RIN 0910-AF38

6. “OTC -- Drug Review Oral Health Care Products,” RIN 0910-AF40

7. “OTC -- Drug Review Weight Control Products,” RIN 0910-AF45

8. “Label Requirement for Food That Has Been Refused Admission Into the United States,” RIN 0910-AF61

9. “Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods,” RIN 0910-AH00

10. “Laboratory Accreditation for Analyses of Foods,” RIN 0910-AH31

11. “Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease,” RIN 0910-AH43

12. “Amendment of Certain Requirements Under 21 CFR 203,” RIN 0910-AH56

13. “Establishment Registration and Product Listing for Tobacco Products,” RIN 0910-AH59

14. “Kid-Appealing Flavors in Tobacco Products; Request for Information,” RIN 0910-AH60

15. “Current Good Manufacturing Practice for Outsourcing Facilities,” RIN 0910-AH61

16. “Radiological Health; Amendments to Records and Report Regulations,” RIN 0910-AH64

17. “Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Veterinary Devices,” RIN 0910-AH66

18. “Updating Public Information Regulations,” RIN 0910-AH69

19. “Revision of Product Jurisdiction Regulations,” RIN 0910-AH71

20. “Record Keeping Requirements Related to Tobacco Product Applications,” RIN 0910-AH74

21. “The Food and Drug Administration Food Safety Modernization Act; Removing Written Assurance Requirements From the Customer Provisions in Certain Implementing Rules,” RIN 0910-AH77

22. “Suspension of Registration of Food Facilities,” RIN 0910-AH79

23. “Amendments to Registration of Food Facilities,” RIN 0910-AH82