

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 300, 330, and 610**

[Docket No. FDA-2015-N-1260]

RIN 0910-AF89

**Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph Proposed Rule; Reopening of the Comment Period****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the comment period for the proposed rule, published in the **Federal Register** of December 23, 2015 (80 FR 79776), revising its regulations on prescription and nonprescription fixed-combination and co-packaged drugs and on combinations of active ingredients under consideration for inclusion in an over-the-counter monograph. FDA is reopening the comment period to permit time for additional comments.

**DATES:** Submit either electronic or written comments by May 18, 2016.**ADDRESSES:** You may submit comments as follows:**Electronic Submissions**

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a

written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

**Written/Paper Submissions**

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2015-N-1260 for "Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph Proposed Rule; Reopening of the Comment Period." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR

56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Diana J. Pomeranz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6208, Silver Spring, MD 20993-0002, 240-402-4654.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 23, 2015 (80 FR 79776), FDA published a proposed rule to revise its regulations on prescription and nonprescription fixed-combination and co-packaged drugs and on combinations of active ingredients under consideration for inclusion in an over-the-counter monograph. Interested persons were originally given until March 22, 2016, to comment on the proposed rule.

On March 21, 2016, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period of 90 days was insufficient to respond fully to FDA's specific requests for comments and to thoroughly evaluate and address pertinent issues. Accordingly, we are reopening the comment period.

Dated: April 13, 2016.

**Leslie Kux,***Associate Commissioner for Policy.*

[FR Doc. 2016-08888 Filed 4-15-16; 8:45 am]

**BILLING CODE 4164-01-P****DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 1**

[REG-109822-15]

RIN 1545-BM70

**Country-by-Country Reporting; Hearing****AGENCY:** Internal Revenue Service (IRS), Treasury.**ACTION:** Notice of a public hearing on notice of proposed rulemaking.

**SUMMARY:** This document provides a notice of public hearing on proposed regulations that would require annual country-by-country reporting by certain United States persons that are the ultimate parent entity of a multinational enterprise group.

**DATES:** The public hearing is being held on Friday, May 13, 2016, at 10 a.m. The IRS must receive outlines of the topics to be discussed at the public hearing by Friday, April 29, 2016.

**ADDRESSES:** The public hearing is being held in the IRS Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue NW., Washington, DC 20224. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building.

Send Submissions to CC:PA:LPD:PR (REG-109822-15), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday to CC:PA:LPD:PR (REG-109822-15), Couriers Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224 or sent electronically via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (IRS REG-109822-15).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Melinda Harvey at (202) 317-6934; concerning submissions of comments, the hearing and/or to be placed on the building access list to attend the hearing Oluwafunmilayo Taylor at (202) 317-6901 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:** The subject of the public hearing is the notice of proposed rulemaking (REG-109822-15) that was published in the **Federal Register** on Wednesday, December 23, 2015 (80 FR 79795).

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing that submitted written comments by March 22, 2016, must submit an outline of the topics to be addressed and the amount of time to be denoted to each topic by Friday, April 29, 2016.

A period of 10 minutes is allotted to each person for presenting oral comments. After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, free of charge, at the hearing or in the Freedom of Information Reading Room (FOIA RR) (Room 1621) which is located at the 11th and Pennsylvania Avenue NW.,

entrance, 1111 Constitution Avenue NW., Washington, DC 20224.

Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

**Martin V. Franks,**

*Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).*

[FR Doc. 2016-08882 Filed 4-15-16; 8:45 am]

**BILLING CODE 4830-01-P**

## DEPARTMENT OF EDUCATION

### 34 CFR Chapter II

[Docket ID ED-2016-OESE-0004; CFDA Number: 84.368A.]

#### Proposed Priorities—Enhanced Assessment Instruments

**AGENCY:** Office of Elementary and Secondary Education, Department of Education.

**ACTION:** Proposed priorities.

**SUMMARY:** The Assistant Secretary for Elementary and Secondary Education proposes priorities under the Enhanced Assessment Instruments Grant program, also called the Enhanced Assessment Grants (EAG) program. The Assistant Secretary may use one or more of these priorities for competitions using funds from fiscal year (FY) 2016 and later years. Depending on the availability of funds and the use of other priorities under the EAG authority, the Assistant Secretary may also choose not to use one or more of these priorities for competitions using funds from FY 2016 and later years. These proposed priorities are designed to support projects to improve States' assessment systems.

**DATES:** We must receive your comments on or before May 18, 2016.

**ADDRESSES:** Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID and the term "Enhanced Assessment Grants—Comments" at the top of your comments.

• *Federal eRulemaking Portal:* Go to [www.regulations.gov](http://www.regulations.gov) to submit your comments electronically. Information on using [Regulations.gov](http://Regulations.gov), including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the "Help" tab.

• *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about these proposed priorities, address them to the Office of Elementary and Secondary Education, Attention: Enhanced Assessment Grants—Comments, U.S. Department of Education, 400 Maryland Avenue SW., Room 3e124, Washington, DC 20202-6132.

**Privacy Note:** The Department of Education's (Department's) policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov). Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

**FOR FURTHER INFORMATION CONTACT:** Donald Peasley. Telephone: (202) 453-7982 or by email: [donald.peasley@ed.gov](mailto:donald.peasley@ed.gov).

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

#### SUPPLEMENTARY INFORMATION:

*Invitation to Comment:* We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priorities, we urge you to identify clearly the specific proposed priority that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from these proposed priorities. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about these proposed priorities by accessing [regulations.gov](http://regulations.gov). You may also inspect the comments in room 3e124, 400 Maryland Avenue SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

*Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record:* On request we will