

scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (g)(2). The applicant, Swedish Match North America Inc., is seeking an order under section 911(g)(1) for each of the 10 products that are the subject of the submitted MRTPAs.

An order under section 911(g)(1) of the FD&C Act is for a modified risk tobacco product that significantly reduces harm and the risk of tobacco-related disease to individual tobacco users; and benefits the health of the population as a whole. A person seeking an order under section 911(g)(1) of the FD&C Act must show that the tobacco product, as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and will benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

FDA is issuing this notice to inform the public that MRTPAs submitted by Swedish Match North America Inc. for the following products (identified by FDA Submission Tracking Numbers (STN) (MR0000020—MR0000029)) have been filed and are being made available for public comment for 180 days:

- MR0000020: General Loose, smokeless tobacco, loose snus, 1.59 oz (45g), cardboard can (SKU 4852);
- MR0000021: General Dry Mint Portion Original Mini, smokeless tobacco, snus portions, 0.21 oz (6g), 20—0.3g portions, plastic can (SKU 4800);
- MR0000022: General Portion Original Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24—1g portions, plastic can (SKU 4880);
- MR0000023: General Classic Blend Portion White Large, smokeless tobacco, snus portions, 0.48 oz (13.5g), 15—0.9g portions, plastic can (SKU 4877);
- MR0000024: General Classic Blend Portion White Large, smokeless tobacco, snus portions, 0.38 oz (10.8g), 12—0.9g portions, plastic can (SKU 4878);
- MR0000025: General Mint Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24—1g portions, plastic can (SKU 4352);

- MR0000026: General Nordic Mint Portion White Large, smokeless tobacco, snus portions, 0.48 oz (13.5g), 15—0.9g portions, plastic can (SKU 4876);

- MR0000027: General Nordic Mint Portion White Large, smokeless tobacco, snus portions, 0.38 oz (10.8g), 12—0.9g portions, plastic can (SKU 4875);

- MR0000028: General Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24—1g portions, plastic can (SKU 4881); and

- MR0000029: General Wintergreen Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24—1g portions, plastic can (SKU 4882).

FDA believes a 180-day comment period is appropriate because of the volume and complexity of the material being posted in the applications. If you submit comments that apply to some but not all 10 of the products, FDA asks that you identify the applicable product(s) using the STNs listed in this document in your comments. To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is placing the MRTPAs (except for matters in the applications that are trade secrets or otherwise confidential commercial information) that are the subject of this notice on public display at the Division of Dockets Management (see **DATES** and **ADDRESSES**) and making them available electronically (see section III).

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either [http://www.accessdata.fda.gov/Static/widgets/tobacco/SMNA\\_MRTPA\\_FDA-2014-N-1051.html](http://www.accessdata.fda.gov/Static/widgets/tobacco/SMNA_MRTPA_FDA-2014-N-1051.html) or <http://www.regulations.gov>.

Dated: August 22, 2014.

**Peter Lurie,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0007]

### Outsourcing Facility Fee Rates for Fiscal Year 2015; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration is correcting a notice entitled “Outsourcing Facility Fee Rates for Fiscal Year 2015” that appeared in the **Federal Register** of August 1, 2014 (79 FR 44805). The document announced the rates for fiscal year 2015 for the establishment and reinspection fees related to human drug compounding outsourcing facilities that elect to register under the Federal Food, Drug, and Cosmetic Act. The document was published with the incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy, Food and Administration, 10990 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Friday, August 1, 2014, in FR Doc. 2014-18111, the following correction is made:

1. On page 44805, in the first column, in the Docket No. heading, “[Docket No. FDA-2013-N-0007]” is corrected to read “[Docket No. FDA-2014-N-0007]”.

Dated: August 21, 2014.

**Peter Lurie,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 2014-20331 Filed 8-26-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Small Health Care Provider Quality Improvement Program

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of Class Deviation From Competition Requirements for Small Health Care Provider Quality Improvement.

**SUMMARY:** The Office of Rural Health Policy (ORHP) will award program expansion supplemental awards to the current Small Health Care Provider