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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
Silver Spring, MD 20993

MEMORANDUM

From: Matthew R. Holman, Ph.D.
Director, Division of Product Science
Office of Science
Digitally signed by Matthew R. Holman -S
Date: 2015.10.21 14:20:50 -04'00'

Through: Cristi Stark, M.S.
Associate Director, Science Policy
Office of Science
Digitally signed by Cristi L. Stark -S
Date: 2015.10.21 14:23:23 -04'00'

To: File

Subject: Unique Identification of Portioned Moist Snuff and Snus Products

Background

On June 2, 2015, I drafted a memo to outline the properties needed to uniquely identify new and predicate tobacco products in SE Reports. We have received SE Reports for portioned moist snuff or snus products that have not provided all of the properties identified in the June 2015 memo. These SE Reports have led to reconsideration of the properties needed to uniquely identify portioned moist snuff and snus products.

Discussion

The June 2015 memo identifies the following descriptive properties for portioned moist snuff and snus products:

1. Package type
2. Portion count
3. Portion mass¹
4. Portion length
5. Portion width
6. Portion thickness
7. Tobacco cut size

¹ Portion mass is for the tobacco filler only.

Unique Identification of Portioned Moist Snuff and Snus

8. Characterizing flavor

If an applicant provides all of these descriptive properties for a new or predicate tobacco product, the product would be uniquely identified. However, it is also possible to uniquely identify a portioned moist snuff or snus product with only seven of these descriptive properties if *both* of the following criteria are met:

1. Portion mass is provided
2. Two of the three portion dimensions are provided:
 - a. Portion length
 - b. Portion width
 - c. Portion thickness

By specifying portion mass along with two other portion dimensions, the third portion dimension is essentially non-variable. For example, if the portion mass, length, and width are specified for a given product, then the portion thickness is unlikely to vary for the product. In other words, although the portion thickness is not known for the product, the product could not exist with multiple portion thicknesses. Therefore, providing portion mass plus two of the three portion dimensions (along with other specified properties) allows unique identification of portioned moist snuff and snus products.

Conclusion and Recommendation

For new and predicate products in SE Reports that are portioned moist snuff or snus, all of the following properties must be specified by the applicant in order to uniquely identify the products:

1. Package type
2. Portion count
3. Portion mass
4. Tobacco cut size
5. Characterizing flavor
6. Two or three of the following:
 - a. Portion length
 - b. Portion width
 - c. Portion thickness