FDA ALERT

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FDA Issues Proposed Tobacco Product Standard for N-Nitrosonornicotine (NNN) in Finished Smokeless Tobacco Products

By Craig A. Koenigs, Partner

On January 23, 2017, the Food and Drug Administration (FDA) issued a proposed tobacco product standard that would establish a limit of N-nitrosonornicotine (NNN) in finished smokeless tobacco products not to exceed 1.0 microgram per gram of tobacco (Proposed Rule). The Proposed Rule would prohibit any person from manufacturing, distributing, selling, or offering for distribution or sale within the United States, finished smokeless tobacco products that do not comply with this standard. The FDA asserts that it is proposing the standard because NNN is a potent carcinogenic agent found in smokeless tobacco products and is a major contributor to elevated cancer risks associated with smokeless tobacco use.

Comments on the Proposed Rule must be submitted by **April 10, 2017**. Comments on the information collection aspects of the Proposed Rule under the Paperwork Reduction Act of 1995, must be submitted by **February 22, 2017**.

Scope of Proposed Rule

The Proposed Rule would apply to the level of NNN in **finished smokeless tobacco products**.

Smokeless tobacco is defined under the Proposed Rule as "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity." This definition includes moist snuff, dry snuff, snus, chewing tobacco, and some dissolvable tobacco products (Dissolvables). Other Dissolvables **do not** meet the statutory definition of a smokeless tobacco product because they do not contain cut, ground, powdered, or leaf tobacco, but rather, contain nicotine extracted from tobacco. Accordingly, Dissolvables that do not meet the statutory definition of a smokeless tobacco product are not covered by the Proposed Rule.

Finished smokeless tobacco product is defined under the Proposed Rule as "a smokeless tobacco product, including all parts and components, packaged for consumer use, except for components, parts or accessories sold without tobacco. An example of a finished smokeless tobacco product is a tin or can of loose snuff or a pouch containing chewing tobacco."

The Proposed Rule is **not** intended to impose manufacturing restrictions on smokeless tobacco products intended for export.

Limit of NNN

The Proposed Rule would require that the mean level of NNN in any batch of finished smokeless tobacco product not exceed 1.0 microgram per gram (ug/g) of tobacco (on a dry weight basis) at any time through the product's labeled expiration date as determined by specified product testing.

***** The FDA also is considering an alternative approach that includes setting a product standard limit under which the specified NNN level of 1.0 ug/g of tobacco (on a dry weight basis) would apply to all units produced from the entire batch, rather than to a per-batch mean. This alternative approach would thereby require the manufacturer to ensure compliance of each unit made from a batch despite some expected random variation of the NNN level between units. The FDA also is inviting comment on the alternative approach.

Expiration Date

The Proposed Rule would require that all finished smokeless tobacco products have an expiration date established by stability testing, which expiration date could be no later than the final date the manufacturer can demonstrate that the NNN level in the subject product conforms to the product standard limit when the product is stored under its intended conditions (e.g., room temperature or refrigeration).

Testing

To ensure that finished smokeless tobacco products conform to the product standard, the Proposed Rule would impose batch testing and stability testing requirements on the products. Batch testing would require testing of each batch of finished smokeless tobacco product to ensure that the product conforms to the proposed NNN level limits. Stability testing would be required to determine the stability of the NNN level in a finished smokeless tobacco product and to establish and verify the product's expiration date and storage conditions (either room temperature or refrigeration).

The testing could be conducted through use of either: 1) a standard test method entitled, "Determination of N-nitrosonornicotine (NNN) in Smokeless Tobacco and Tobacco Filler by HPLC-MS/MS," which test would be incorporated by reference in the Proposed Rule; or 2) an alternative test method, provided that certain notification, information and other requirements are satisfied for use of the alternative test method.

In addition, the Proposed Rule would require each smokeless tobacco product manufacturer to design and implement sampling plans for batch testing and stability testing. The sampling plan or plans for batch testing must be based on valid statistical rationale to ensure that the finished smokeless tobacco product consistently conforms to the NNN level in the product standard. Similarly, the sampling plan or plans for stability testing must be based on valid statistical rationale to demonstrate that the finished smokeless tobacco product's expiration date is appropriate under the intended storage conditions. The Proposed Rule also would require test samples to be collected and examined in accordance with specified procedures.

Package Labeling

The Proposed Rule would require package labels for all finished smokeless tobacco products to include a manufacturing code, expiration date, and if applicable, storage conditions. The information would be required to appear clearly, legibly and indelibly in English on the label and the information would have to be printed on or permanently affixed to the package in a manner that assures it will remain on the packaging or label through the expected duration of use of the product by the consumer.

Nonconforming Product

Tobacco product manufacturers would be required to establish and maintain procedures for identifying, investigating, segregating, and making disposition decisions about finished smokeless tobacco products that do not conform to the product standard, in order to prevent any nonconforming products from being released for commercial distribution.

Recordkeeping

The Proposed Rule also would require tobacco product manufacturers to establish and maintain a series of records related to the testing, sampling plans, sampling personnel, investigation, and disposition of nonconforming products and certain other requirements related to the manufacture of finished smokeless tobacco products.

Copies of all records required under the Proposed Rule would have to be retained for a period of not less than four (4) years from the date of commercial distribution of the finished smokeless tobacco product that is the subject of the record. One exception would be for records relating to alternative test methods, which would have to be retained for a period of not less than four (4) years after the last date the alternative test method that is the subject of the record is used.

Proposed Effective Date

FDA proposes that the effective date of any final rule on the tobacco product standard for NNN based on this Proposed Rule should be three (3) years after the date of publication of the final rule.

Premarket Review

Notably, the Proposed Rule states that a smokeless tobacco product that is modified to comply with the product standard **would** be considered a "new tobacco product" and subject to premarket review.

Premarket review of "new tobacco products" can take any of the following three pathways: 1) submission of a request for an exemption from substantial equivalence (SE) requirements (SE Exemption Request) and receipt of an SE exemption determination; 2) submission of an SE report (SE Report) and receipt of an SE order; or 3) submission of a premarket tobacco product application (PMTA) and receipt of a marketing authorization order.

FDA is considering whether it might be able to review a reduced, specific set of information for smokeless tobacco products eligible for an SE Report, where the SE Report demonstrates that the only modifications made to the new product were made to comply with the NNN product standard and do not present different questions of public health.

Based on the proposed effective date, the FDA believes that manufacturers would have adequate time following issuance of any final rule on the product standard to submit and obtain premarket approval prior to the effective date.

Executive Order on Regulations

On January 30, 2017, President Trump signed Executive Order 13771, entitled "Reducing Regulation and Controlling Regulatory Costs." The purpose of the Executive Order is to decrease regulatory burdens on private businesses and responsibly manage the expenditure of public funds related to regulation. In furtherance of that purpose, the Executive Order states, "it is important that for every one new regulation issued, at least two prior regulations be identified for elimination, and that the cost of planned regulations be prudently managed and controlled through the budgeting process." It is unclear at this time how this Executive Order might affect the Proposed Rule.

Please contact one of the listed Roetzel attorneys for further information on this alert or if you would like any assistance preparing comments or responding to the Proposed Rule.

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