

Tobacco Product Standard: NNN Level of Finished Smokeless Tobacco Products

0910-NEW

RIN ()
SUPPORTING STATEMENT

Terms of Clearance: NA

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Tobacco Control Act was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and providing FDA with the authority to regulate tobacco products (Pub. L. 111-31; 123 Stat. 1776). Among the authorities provided to FDA is the authority to establish tobacco product standards. To establish a tobacco product standard, section 907(a)(3)(A) & (B) of the FD&C Act requires that we find that the standard is appropriate for the protection of the public health. FDA is issuing this proposed rule to address the harm caused by the toxicant N-nitrosornicotine (NNN) in smokeless tobacco products.

2. Purpose and Use of the Information Collection

The respondents are manufacturers of smokeless tobacco products. The provisions of this standard would apply to finished smokeless tobacco products. Finished smokeless tobacco product means a smokeless tobacco product, including all parts and components, packaged for consumer use, except for components, parts, or accessories sold without tobacco.

Products with higher NNN levels pose higher risks of cancer and FDA finds that establishing a NNN limit in finished smokeless tobacco products is appropriate for the protection of the public health. Proposed § 1132.10 would require that the mean level of NNN in any batch of finished smokeless tobacco products not exceed 1.0 µg/g of tobacco (on a dry weight basis) at any time through the product's labeled expiration date as determined by testing in compliance with § 1132.12. Proposed §§ 1132.12, 1132.14, 1132.16, and 1132.18 would establish product testing and sampling plan requirements. Proposed § 1132.12 would require two types of testing for smokeless tobacco products—stability testing and batch testing. Proposed § 1132.12(a) would require initial and annual stability testing to assess the stability of the NNN level in finished smokeless tobacco products and to establish and verify the product's expiration date and storage conditions (either room temperature or refrigeration). Proposed § 1132.12(b) would require manufacturers to conduct batch testing on each batch of finished smokeless tobacco product to determine whether the products conform to the proposed NNN limit. Proposed § 1132.12(c) would require the tobacco product manufacturer to document all testing. Proposed §§ 1132.14 and 1132.16 would establish the standard and alternative

test methods. If a tobacco product manufacturer were to choose not to use the standard test method in § 1132.14 to test its smokeless tobacco products, the manufacturer would be required to use a validated alternative test method that conforms to the requirements of proposed § 1132.16. Proposed § 1132.16(a) would require that, before using a validated alternative test method, the manufacturer notify the Center for Tobacco Products.

3. Use of Improved Information Technology and Burden Reduction

FDA encourages electronic submission. FDA estimates that 87% of those respondents who chose to submit an alternative test method will use electronic means.

Explain any consideration given to use technology to reduce the burden. How can FDA use technology to improve this information collection? Explain, in detail, any obstacles or mitigating circumstances that prevent FDA from incorporating electronic submission.

Electronic respondent reporting has become an important issue at OMB. The Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII, was signed into law on October 21, 1998. GPEA requires Federal agencies, to allow individuals or entities that deal with the agencies the option to submit information or transact business with the agency electronically, when practicable, and to maintain records electronically, when practicable. Its goal is to encourage agencies to incorporate technologically improved respondent reporting as this process typically lowers burden to the respondent. Therefore, all decisions NOT to utilize electronic respondent reporting must be strongly justified.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative. Section 907 of the FD&C Act is the only legislation which authorizes the federal government to promulgate tobacco product standards that are appropriate for the protection of the public health. The FDA is the only Federal agency responsible for smokeless tobacco product testing, and the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. Therefore, no duplication of data exists.

5. Impact on Small Businesses or Other Small Entities

FDA anticipates that the proposed rule would have an impact on a number of small entities. Approximately 72 percent of entities that would be affected by the proposed rule are estimated to be small.

The proposed rule offers regulatory alternatives, Alternative 2 (establish a less stringent NNN standard), and Alternative 3 (extension of the effective date) that would reduce costs for affected entities both offer potential regulatory relief options for small businesses.

6. Consequences of Collecting the Information Less Frequently

FDA issued this proposed standard to address the harm to smokeless tobacco users caused by NNN by establishing a limit for NNN in finished smokeless tobacco products (see proposed § 1132.10), thereby reducing exposure to this harmful toxicant. NNN levels vary substantially across subcategories of smokeless tobacco products (e.g., moist snuff, chewing tobacco, dry snuff) and within product subcategories (e.g., moist snuff). If FDA collects this information less frequently products with higher NNN levels will be on the market. Higher NNN levels pose higher risks of cancer, and establishing a limit for NNN in finished smokeless tobacco products is appropriate for the protection of the public health.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of January 23, 2017 (82 FR 8004).

There was no impact or overlap with other agencies that would necessitate obtaining their views regarding recordkeeping, data availability, disclosure, reporting format or other above outlined items for this notice of proposed rulemaking/information collection.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

Section 906(c) of the FD&C Act prohibits FDA from disclosing any information reported to FDA if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers of employees concerned with carrying out the tobacco products chapter of the FD&C Act and, when relevant, in any proceeding under the tobacco products chapter of the FD&C Act. Section 301(j) of the FD&C Act generally prohibits release of trade secret information obtained by FDA outside of the Department of Health and Human Services, except to courts when relevant in any judicial proceeding under the FD&C Act and to Congress in response to an authorized Congressional request.

FDA's general policy on disclosure of FDA records is contained in 21 CFR 20.20. Information is handled, stored and disposed of in accordance with records management requirements (44 U.S.C. 3301)

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs.

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

"21 CFR Part"	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§1132.16 Alternative Test Method (FDA Form 3979)	23	1	23	20	460
§1132.16 Waiver from Electronic Submission	2	1	2	.75	2
Total					0

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² The burden in the reporting chart corresponds to Table 23 "Estimated Costs to Industry Associated with Notifications to FDA Regarding Use of Alternative Testing Methods" in the RIA.

Table 2.--Estimated Annual Recordkeeping Burden

Activity (units)	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Change in process (Formulations)	68	1	68	8	544
Ingredient change (Formulations)	28	1	28	8	224
No change (Formulations)	60	1	60	4	240
Labeling records, annual after year 1 (UPCs)	1255	1	1255	2	2,510
Initial Stability Testing records	23	8	184	4	736

(Manufacturers)					
Annual Stability Testing records (Manufacturers)	23	3	69	4	276
Batch Testing (products)	784	28	21,952	4	87,808
Batch Testing Records (Manufacturers)	23	1	23	4	92
Procedures for nonconforming products and related investigations (Manufacturers)	23	1	23	4	92
Notifications, alternate testing methods (Manufacturers)	23	2	46	0.75	35
Total					00

¹The burden in the recordkeeping chart corresponds to Table 24 “Estimated Recordkeeping Costs to Industry” and Table 13 “Estimated Number of Batch Tests” in the RIA.

Table 3.--Estimated Annual Third-Party Disclosure Burden

Activity (units)	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Package Labeling Change Minor (UPCs)	459	1	459	10	4,590
Package Labeling Change Major (UPCs)	8	1	8	23	184
Initial Stability Testing (one time) (Products)	784	168	131,712	2	263,424
Initial Stability Testing (recurring) (Products)	784	6.72	5,268	2	10,536

Annual Stability Testing (Products)	784	60.48	47,416	2	94,832
Sampling Plans (Products)	784	1	784	2	1,568
Total					0

¹ The burden in the third-party disclosure chart corresponds to Table 12 “Estimated Costs Associated with Proposed Stability Testing Requirements” and Table 15 “Products with Expiration and Storage Information” in the RIA.

FDA’s burden estimates are based on the regulatory impact analysis, agency expertise, registration and listing data, company revenue information from Dunn & Bradstreet, and comparing to other online sources in order to categorize the entities and number of products. Table 9 describes the annual reporting burden as a result of the requirements proposed in § 1132.16 submitting a notification of an alternative test method and requesting a waiver from electronic submission of such a notification. FDA estimates that it will receive 23 notifications for alternative test methods using FDA form 3979 (Ref. 145) for a total of 460 hours. Because some of the manufacturers may currently be conducting these reports, the RIA anticipates that there would be between 1 and 23 manufacturers affected. For PRA purposes we have used the high estimate of 23. Although FDA encourages electronic submission, FDA estimates that 2 respondents will submit a waiver request from electronic submission. Therefore, the total estimated reporting burden for this proposed rule is 462 hours.

Table 10 outlines the recordkeeping requirements that are proposed in §1132.32. We note that recordkeeping time burden activities are derived from the respective models (RTI International, 2015a; RTI International, 2015a; RTI International, 2015b). FDA estimates recordkeeping time burden related to product reformulation (change in process, ingredient change, and no change) to involve 156 formulations for total of 1,008 hours. For recordkeeping burden related to certain labeling records, FDA estimates that after year one 1,255 affected UPC records will be kept annually for a total of 2,510 hours. The number of Universal Product Codes (UPCs) subject to these recordkeeping requirements is determined by multiplying the number of UPCs in each product category by the percent of products with expiration date information.

We estimate that batch testing will be conducted for 784 products (21,952 tests per year) for a total of 87,808 hours. Proposed §1132.32 requires records to be maintained for stability and batch tests. FDA estimates that 23 manufacturers will maintain records related to initial stability testing, annual stability testing, and batch testing for a total of 1104 hours. Records are also required to be maintained of procedures for nonconforming products and related investigations. We estimate that 23 manufacturers will maintain these records for a total of 92 hours. Proposed §1132.32 requires manufacturers to maintain all notifications of an alternative test method. We estimate that 23 manufacturers will maintain these records for a total of 35 burden hours. Therefore, the total estimated recordkeeping hours are 92,557.

Table 11 represents third party disclosures (package labeling) that a respondent must display. This table also covers the proposed stability testing that must occur for the label. Labeling burden is estimated by using data on the number of active UPCs from Nielsen Inc., and

the estimated percentage of products with expiration and storage information come from FDA Registration and Listing database (as of March 1, 2016). To derive the number of UPCs subject to a labeling change that includes storage information, we assume that only those products that are currently refrigerated but for which we did not find evidence that the labeling exists would incur such labeling change. Thus, we estimate that these different products that would likely be affected by labeling changes would include up to 467 UPCs (derived by assuming that each product would be associated with one unique UPC).

Since all products already have either an expiration date or a manufactured on date, adding an expiration date or storage conditions to labeling would be considered a minor change if product label redesign is not needed and major if product label redesign is needed. FDA believes that labeling changes associated with adding storage information is assumed to be “major” to incorporate uncertainty regarding product label redesign. We estimate that 459 affected UPCs will undergo minor labeling changes for a total of 4,590 hours. Additionally, FDA estimates that 8 affected UPCs will undergo major labeling changes regarding storage information for a total of 184 hours.

Since establishing and verifying a product’s expiration date and storage conditions on a label requires actual stability testing we categorize this burden under third party disclosures. For PRA purposes we have categorized stability testing under third party disclosures. For example, in accordance with § 1132.30 a package label would need to have the expiration date for the product. Prior to completing initial stability testing, the manufacturer might not know what the appropriate expiration date would be. Since the testing will inform the label we believe it is appropriate for the burden to fall under this category. We estimate that 784 products would undergo initial stability testing, and annual stability testing each year thereafter. FDA estimates that in year 1 there would be 131,712 initial tests for a total of 263,424 hours. After the first year we estimate that there would be 5,268 initial tests for a total of 10,536 hours. After the initial testing we expect 47,416 annual tests per year for total of 94,832 hours.

FDA included sampling plans in the third party disclosure chart because each tobacco product manufacturer would be required to demonstrate that the finished smokeless tobacco product’s expiration date (on the label) is appropriate under the intended storage conditions, and to do so the manufacturer would conduct testing pursuant to sampling plans. In developing a sampling plan for NNN in smokeless tobacco products a manufacturer must take into account the size of a batch, the variation of NNN in their product, the margin of error around their analytical techniques, and any other variables they can justify as pertinent to their calculation. While the development of a sampling plan would require some data analysis and determination of assumptions, we believe that the development of a sampling plan could cover multiple products. In addition once a sampling plan had been developed we believe that there would be significant redundancy in the development of subsequent plans which would reduce the time needed to complete them. Ultimately we have estimated that the time for the development of a sampling plan would average 2 hours per product for a total of 1,568 hours. Therefore, the total third party disclosure burden is estimated to be 370,360 hours.

FDA estimates that the total burden imposed by these proposed requirements will be 463,379 hours (462 reporting, 92,557 recordkeeping, and 370,360 third party disclosures).

This proposed rule also refers to previously approved collections of information found in FDA regulations. The collections of information in section 905(j) of the FD&C Act (substantial equivalence reports) have been approved under OMB control number 0910-0673.

12b. Annualized Cost Burden Estimate

	Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs	Source (RIA)
Annual Reporting	§1132.16 Alternative Test Method (FDA Form 3979)	460	73.04	\$33,598	Table 24 Alternative Testing Methods
	§1132.16 Waiver from Electronic Submission	2	73.04	\$146	
Annual Recordkeeping	Change in process (Formulations)	544	80	\$43,520	CFSSAN Reformulation Cost Model
	Ingredient change (Formulations)	224	80	\$17,920	
	No change (Formulations)	240	80	\$19,200	
	Labeling records, annual after year 1 (UPCs)	2,510	77.84	\$195,378	Table 25 Recordkeeping Costs
	Initial Stability Testing records (Manufacturers)	736	77.84	\$57,290	
	Annual Stability Testing records (Manufacturers)	276	77.84	\$21,484	
	Batch Testing (products)	87,808	77.84	\$6,834,975	
	Batch Testing Records (Manufacturers)	92	77.84	\$7,161	
	Procedures for nonconforming products and related investigations (Manufacturers)	92	77.84	\$7,161	
	Notifications, alternate testing methods (Manufacturers)	35	77.84	\$2,724	
Third Party Disclosure	Package Labeling Change Minor (UPCs)	4,590	80	\$367,200	FDA Labeling Cost Model
	Package Labeling Change Major (UPCs)	184	80	\$14,720	
	Initial Stability Testing (one time) (Products)	263,424	77.84	\$20,504,924	Table 25 Recordkeeping

Initial Stability Testing (recurring) (Products)	10,536	77.84	\$820,122	eping Costs
Annual Stability Testing (Products)	94,832	77.84	\$7,381,723	
Sampling Plans (Products)	1,568	77.84	\$122,053	
Total	468,153		0	

FDA has estimated that depending on the activity the wage per hour is between 73.04 and \$80. The rates are adjusted for benefits and overhead,. FDA estimates the cost to respondents is \$36,451,299. This figure was derived by multiplying the burden hours by the hourly rates.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated time to review a notification is 32 hours and it is based on the time that FDA anticipates it would take to review the detailed notification. Total costs are thus calculated by multiplying the estimated time to review the notification by the hourly wage and number of notifications. The RIA estimate costs in Year 1 range from \$3,840 (=1*\$120*32) to \$88,320 (=23*\$120*32). For these purposed FDA estimates the high range of 23 notifications (\$88,320)/3. Therefore the annual cost to the government is \$29,440.

15. Explanation for Program Changes or Adjustments

This is a new proposed rule.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency has no plans for the tabulation and publication of this collection of information.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption from display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.