the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

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(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 24, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–4556 Filed 2–25–11; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0542]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information Request Regarding Dissolvable Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by April 1, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title "Information Request Regarding Dissolvable Tobacco Products." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Information Request Regarding Dissolvable Tobacco Products—(OMB Control Number 0910–NEW)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 917 of the Tobacco Control Act (21 U.S.C. 387q) requires the Secretary of Health and Human Services (the Secretary) to establish a Tobacco Products Scientific Advisory Committee (TPSAC). Section 907(f) of the Tobacco Control Act (21 U.S.C. 387g(f)) requires the TPSAC to submit a report and recommendations to the Secretary on the impact of the use of dissolvable tobacco products on the public health, including such use among children. To ensure a comprehensive review of this issue, FDA is requesting tobacco industry documents and information to support the work of TPSAC. Under section 907(f), TPSAC must submit its report and recommendations to the Secretary within 2 years after its establishment, or March 22, 2012.

In order to provide TPSAC with the information it needs to carry out its statutory obligation, FDA is requesting that tobacco companies submit information under section 904(b) of the Tobacco Control Act (21 U.S.C. 387d(b)) pertaining to documents and underlying scientific and financial information relating to research, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on a specified set of topics. For the purposes of this request, "research" may include, but is not limited to, focus groups, surveys, experimental clinical studies, postmarketing surveillance, toxicological and biochemical assays, taste panels, and assessments of the effectiveness of product marketing practices. Topics for which information relating to dissolvable tobacco products is requested are marketing research; marketing practices; effectiveness of marketing practices; and health, toxicological, behavioral, and physiological effects. FDA's request for documents related to dissolvable tobacco products includes, but is not limited to products for research, investigational use, developmental studies, test marketing, and/or commercial marketing, and also to the components, parts, or accessories of such products.

In the **Federal Register** of October 25, 2010 (75 FR 65490), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received eight comments from seven commenters; six comments pertaining to the notice, and two comments pertaining to the information collection. Six comments were beyond the scope of this information request (*e.g.,* tobacco is dangerous, dissolvable tobacco products are appealing to children, FDA should let the market prevail, FDA reviewers and TPSAC are not impartial). Comments relevant to the information request are addressed in this document.

One commenter suggested that they would like to withhold proprietary information or have FDA mark the information received as "confidential and proprietary", and would like FDA to explicitly state in the letter that FDA does not require nor accept publically available information. The commenter would like FDA to accept submission of lists, summaries, and abstracts as a first pass so FDA could then decide which documents it really needs, and would like FDA to better explain what it is looking for with regard to internal reports. The commenter would like FDA to restrict submissions to primary research data, and would like FDA to provide specific instructions for the citing of previously submitted documents so they can be fully referenced. FDA's response is that, with regard to confidential and proprietary information, documents submitted under section 904(b) of the FD&C Act may include, but are not limited to a company's non-public, trade secret, or confidential commercial information. FDA also notes that several laws govern maintaining the confidentiality of new tobacco product information submitted under section 904(b), including sections 301(j) and 906(c) of the FD&C Act (21 U.S.C. 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as FDA's implementing regulations. FDA's general regulations concerning the public availability of FDA's records are contained in 21 CFR part 20. With

regard to the submission of summary lists instead of documents, it is the responsibility of manufacturers and importers to identify and submit all documents that are responsive to a request under section 904(b). Information which could be responsive to this section 904(b) request that has been previously provided to FDA does not have to be re-submitted as long as the document is fully referenced with information including file name and file extension, Bates number (begin Bates number to end Bates number), the date of submission, and relevant page numbers. If the documents were previously submitted to FDA under the section 904(a)(1), 904(c)(1), 904(c)(2) or 904(c)(3) requirement to submit listings of ingredients in tobacco products, FDA asks that the respondent please provide the date of submission, section under which the document was submitted, and the tobacco product brand/subbrand name and product identification number.

One commenter indicated that they bear responsibility for coordinating the implementation of the Tobacco Control Act for itself and its subsidiaries, and that they had already provided FDA with substantial information regarding dissolvable tobacco products in response to a February 1, 2010, request from FDA for this information. They also are concerned that FDA does not appear to give meaningful consideration to the burden imposed by FDA's requests, or to respondent's ideas for more efficient collections of information. The commenter hoped that FDA will consider the comments received as it continues to formulate future document and information collection requests and realize that FDA has seriously underestimated the time and cost burden to gather, review, and produce the requested documents. In addition, the commenter felt that FDA did not adequately explain how it calculated the estimated burden for respondents, as the 230 burden hours listed in the 60-day **Federal Register** notice may be accurate for manufacturers conducting peripheral research, but may not be that accurate for a large tobacco manufacturer. The commenter stated that they estimate it will take 10,000 hours to produce the documents FDA requested related to dissolvable tobacco products. The commenter stated that FDA has exhibited a pattern of underestimating burden associated with document production requests in the past, and that this collection runs counter to the PRA because the collection does not minimize respondent burden, and will have no practical utility to FDA. The commenter also asked that FDA, rather than respondents, identify previously submitted documents because they should be able to produce this information using commonly available commercial software. The commenter re-emphasized that FDA and TPSAC would be unable to process the sheer volume of this information, so it has little practical utility and does not minimize paperwork burden in violation of the PRA. They ask that FDA revise its estimated time and burden on manufacturers, allow time for meaningful review, and maximize the practical utility of this collection. In estimating the initial burden for this collection, FDA utilized its staff expertise and previous experience with similar types of Agency collections to determine the burden. While FDA understands that there appears to be a large discrepancy in burden between this commenter's estimate and FDA's estimate, FDA did follow a methodology to determine as accurate an estimate of average burden as possible. However, due to the comments received for this information collection and other comments submitted by stakeholders, FDA has revised the burden for this collection. Information received by the public directly and in response to requests for comments will assist FDA in determining more accurate burden estimates in the future. With regard to the submission of documents previously, it is the responsibility of manufacturers and importers to identify and submit all documents that are responsive to a request under section 904(b). As stated in the 60-day **Federal Register** notice (75 FR 65490) and letter, information responsive to this section 904(b) request which has been previously submitted to FDA under the Tobacco Control Act does not have to be re-submitted as long as the document is fully referenced.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours	Total capital costs
Submission of Dissolvable Tobacco Product Documents Under Section 904(b)						
Large Tobacco Manufacturers or Importers	3	1	3	7,500	22,500	$435
Small to Medium Tobacco Product Manufacturers or Importers	7	1	7	230	1,610	324
Submission of Letter indicating no documents available	110	1	110	1	110	165
Total	120		120		24,220	924

FDA has adjusted the burden for this information collection based on stakeholder and public comments received for this collection of information. Originally, FDA estimated that 10 tobacco manufacturers would be responsible for submitting documents, and that their burden would average 230 hours each. After reviewing comments, FDA still maintains that 10 tobacco manufacturers will be responsible for submitting documents, and has now broken the burden into three tiers—large manufacturers and importers, small to medium manufacturers and importers, and manufacturers who are only required to submit a letter indicating that they have no tobacco documents to submit. As shown in table 1, FDA now estimates that 3 large manufacturers are estimated to take approximately 7,500 hours apiece to provide dissolvable tobacco product documents, 7 small to medium manufactures are estimated to take approximately 230 hours apiece to provide dissolvable tobacco product documents, and 110 other manufacturers who do not have documents, do not manufacture dissolvable tobacco products, or do not

anticipate manufacturing dissolvable tobacco products will take approximately 1 hour to draft and send a letter to FDA indicating that they do not have documents to submit. These estimates were derived based upon FDA experience and feedback provided by public and stakeholder comments.

The capital costs associated with this collection pertain to the postage for mailing documents in electronic or paper formats. Estimating these costs is problematic because the costs will vary depending on the size of the document production (*e.g.* one binder of documents vs. numerous boxes of paper) and the media type (*e.g.,* compact disk (CD) or digital video disk) chosen to submit documents. Currently, we cannot identify how many documents will be submitted per response.

Some sample postage costs are shown for different types of packages:

- 10 CDs in a flat envelope weighing 30 ounces: approximately $8.00 using first class business mail
- 5-pound parcel containing paper documents: approximately $12 using business parcel post mail and delivering to the furthest delivery zone
- 10-pound parcel containing paper documents: approximately $17 using business parcel mail and delivering to the furthest delivery zone
- 50-pound parcel containing paper documents: approximately $52 using business parcel post mail and delivering to the furthest delivery zone.

FDA estimates the capital costs associated with this document submission to be $924. The capital costs determined by this estimate are based upon 3 submissions for large manufacturers, 7 submissions for small to medium manufacturers, and 110 submissions of 1 letter apiece for those who do not either manufacture dissolvable tobacco products or have documents pertaining to the manufacture of dissolvable tobacco products.

For the three large manufacturers, it is estimated that each manufacturer will submit their documents electronically on the equivalent of one 500-gigabyte external hard drive of data. This is estimated to cost approximately $125 per drive, and $20 to ship the drive, for a total of $435 (3 manufacturers × [$125 + $20]).

For the 7 small to medium sized manufacturers, it is estimated that 5 manufacturers (about 71 percent) will submit their documents electronically on the equivalent of 10 CD–ROMs. This is estimated to cost $20 for the 10 CD–ROM spindle, and $8 to ship each group of 10 CDs per envelope for a total of $140 (5 manufacturers × [$20 + $8]). The remaining two manufacturers will submit their documents via paper, which is estimated to cost $184 (2 manufacturers × [$40 cost of one box of paper + $52 to ship the box of paper]). The total capital cost for small to medium manufacturers, therefore, is estimated to be $324 ($140 + $184).

For the remaining 110 manufacturers who must submit a letter to FDA indicating that they do not have any documents, it is estimated that each manufacturer will use $1 of paper products and pay postage approximating a rounded figure of $0.50 for a total of $165 (110 manufacturers × [$1.00 + $0.50]). Therefore, FDA estimates the total capital costs associated with this document submission to be $924.

Dated: February 24, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–4613 Filed 3–1–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0201]

Determination That NILSTAT (Nystatin Powder (Oral, 100%)) Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that NILSTAT (nystatin powder (oral, 100%)) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nystatin powder (oral, 100%) if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Jennifer L. Stevens, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6316, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

NILSTAT (nystatin powder (oral, 100%)) is the subject of NDA 050576, held by Dava Pharmaceuticals, Inc., and was initially approved on December 22, 1983. NILSTAT is indicated for the treatment of intestinal and oral cavity infections caused by *Candida (Monilia) albicans*. NILSTAT (nystatin powder (oral, 100%)) is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Paddock Laboratories, Inc., submitted a citizen petition dated April 8, 2010 (Docket No. FDA–2010–P–0201), under 21 CFR 10.30, requesting that the Agency determine whether NILSTAT (nystatin powder (oral, 100%)) was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that NILSTAT (nystatin powder (oral, 100%)) was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NILSTAT (nystatin powder (oral, 100%)) was