

nominations must be compounded using a bulk drug substance rather than the approved drug product.

#### IV. Other Issues Raised in Nominations

Some of the bulk drug substance nominations included in this notice state that there could be a benefit gained from providing drug products containing each of these bulk drug substances that do not require dilution or reconstitution prior to administration. More broadly, as explained above, when a bulk drug substance is a component of an approved drug, FDA asks whether there is a basis to conclude that an attribute of each approved drug product makes each one medically unsuitable to treat certain patients for their condition, an interpretation that protects patients and the integrity of the drug approval process. The nominations do not show that the approved drug product, when not manufactured in the ready-to-use form, is medically unsuitable for certain patients. Nor do the nominations establish that drug products in the relevant concentrations, including ready-to-use products, cannot be prepared from the approved drug products. Rather, they propose to compound a ready-to-use product from bulk drug substances to seek improved efficiency for prescribers or healthcare providers, or to address the possibility that the approved drug might be mishandled by a medical professional, neither of which falls within the meaning of clinical need to compound a drug product using a bulk drug substance.

Some of the nominations for the substances in this notice include statements that these substances should be added to the 503B Bulks List because compounding from the bulk drug substance could help outsourcing facilities address drug shortages and supply disruptions of approved drugs. As noted above, section 503B of the FD&C Act contains a separate provision for compounding from bulk drug substances to address a drug shortage, and we do not interpret the other price- and supply-related issues advanced by the nominations to be within the meaning of "clinical need" for compounding with a bulk drug substance.<sup>51</sup>

<sup>51</sup> Please see the final guidance entitled "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act" (503B Bulks Evaluation Guidance) (84 FR 7390); available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM602276.pdf> and the Federal Register notice entitled "List of Bulk Drug

Some of the nominations for the substances in this notice assert that it would be preferable to compound a drug product using a bulk drug substance rather than using an approved drug product; however, they do not take the position or provide support for the position that a bulk drug substance must be used to prepare these concentrations.<sup>52</sup>

#### V. Conclusion

For the reasons stated above, we find no basis to conclude that there is a clinical need for outsourcing facilities to compound drug products using the bulk drug substances dipyrindamole, ephedrine sulfate, famotidine, hydralazine hydrochloride, methacholine chloride, sodium bicarbonate, sodium tetradecyl sulfate, trypan blue, and vecuronium bromide. We therefore propose to not include dipyrindamole, ephedrine sulfate, famotidine, hydralazine hydrochloride, methacholine chloride, sodium bicarbonate, sodium tetradecyl sulfate, trypan blue, and vecuronium bromide on the 503B Bulks List.

Dated: August 27, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0717]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns

**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

Substances for Which There Is a Clinical Need Under Section 503B of the Federal Food, Drug, and Cosmetic Act" available at <https://www.federalregister.gov/documents/2019/03/04/2019-03810/list-of-bulk-drug-substances-for-which-there-is-a-clinical-need-under-section-503b-of-the-federal>.

<sup>52</sup> For example, the nominations do not take the position or provide support for the position that a drug product prepared by starting with the approved drug would be unsuitable for administration.

Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by October 3, 2019.

**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 emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0753. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

#### Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns

OMB Control Number 0910-0753—Extension

#### Overview of the Evaluation Studies

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing youth-targeted public education campaigns to help prevent tobacco use among youth and thereby reduce the public health burden of tobacco. The campaigns feature televised advertisements along with complementary ads on radio, on the internet, in print, and through other forms of media.

Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions. Comprehensive evaluation of FDA's

public education campaigns will be used to document whether the intended audience is aware of and understands campaign messages; and whether campaign exposure influences beliefs about tobacco, susceptibility to tobacco use, and tobacco use behavior. All the information collected is integral to that evaluation.

FDA conducted three studies to evaluate the effectiveness of its youth tobacco prevention campaigns: (1) An outcome evaluation study of its General Market Youth Tobacco Prevention Campaign, (2) an outcome evaluation of the Rural Male Youth Smokeless Tobacco Campaign, and (3) a media tracking survey. The timing of these studies follows the multiple, discrete waves of media advertising planned for the campaigns. The outcome evaluation of the smokeless tobacco campaign and the media tracking survey are now complete, while evaluation of the General Market Youth Tobacco Prevention campaign is ongoing.

#### The General Market Youth Tobacco Prevention Campaign

The General Market Youth Tobacco Prevention Campaign targets youth who are at risk for smoking, or who have experimented with smoking but not progressed to regular smoking. The campaign evaluation consists of surveys

conducted with two cohorts of youth and their parents or guardians. Each cohort consists of an initial baseline survey of youth aged 11 to 16, and followup surveys of the same youth at approximate 8-month intervals. At baseline, surveys are also conducted with the parent or legal guardian of each youth to collect data on household characteristics and media use. Because youth age over the study period, the age range of youth and young adults among whom we collect data over the study period are aged 11 to 18.

Data collection associated with the first cohort, including a baseline survey and four followup surveys, is complete. We have also completed baseline and first followup data collection for the second cohort. We are planning two additional followup surveys of youth in the second cohort.

#### Methods Used for the Evaluation Study

All information for the General Market campaign evaluation is being collected through in-person and web-based questionnaires. Youth respondents were recruited from a probability sample drawn from 90 U.S. media markets gathered using an address-based postal mail sampling of U.S. households. Participation in the study is voluntary.

#### Purpose of the Evaluation Studies

The studies are being conducted in support of the provisions of the Tobacco Control Act, which require FDA to protect the public health and reduce tobacco use by minors. The information being collected is necessary to inform FDA's efforts towards those goals and to measure the effectiveness and public health impact of the campaigns. Data from the outcome evaluation of the General Market and Rural Male Youth Smokeless campaigns are being used to examine statistical associations between exposure to the campaigns and subsequent changes in specific outcomes of interest, which include knowledge, attitudes, beliefs, and intentions related to tobacco use, as well as behavioral outcomes including tobacco use. Data from the media tracking survey are being used to estimate awareness of and exposure to the campaigns among youth nationally as well as among youth in geographic areas targeted by the campaign.

In the **Federal Register** of May 17, 2019 (84 FR 22499), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received that were not PRA related.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| Type of respondent               | Activity                                                                                                                                                        | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| General Population .....         | Screener and Consent Process (Parent Permission).                                                                                                               | 6,270                 | 1                                  | 6,270                  | .125 (7.5 minutes) .....    | 784         |
| Parent of Youth Baseline Survey. | Telephone Verification Survey .....                                                                                                                             | 627                   | 1                                  | 627                    | .1333 (8 minutes) .....     | 84          |
| Participants .....               | Recruitment Materials—Panel Maintenance Letter, Lead Letter, Survey Invitation Email, Q&As; Study Description; Email Reminders, Reminder Letter, Notifications. | 6,270                 | 1                                  | 6,270                  | .20 (12 minutes) .....      | 1,254       |
| Cohort 2 Youth Assent ...        | Youth Assent under 18 .....                                                                                                                                     | 5,874                 | 1                                  | 5,874                  | .08 (5 minutes) .....       | 470         |
| Cohort 2—Youth Aged 11 to 18.    | Youth Consent 18 and up .....                                                                                                                                   | 396                   | 1                                  | 396                    | .08 (5 minutes) .....       | 32          |
|                                  | Cohort 2—Youth 1st, 2nd, 3rd Followup Questionnaire.                                                                                                            | 6,270                 | 1                                  | 6,270                  | 0.75 (45 minutes) .....     | 4,703       |
| Totals .....                     | .....                                                                                                                                                           | .....                 | .....                              | 25,707                 | .....                       | 7,327       |

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

FDA has revised the burden since publication of the 60-day notice due to the decision to complete data collection for the Media Tracking Survey earlier than originally planned. Therefore, the estimated burden hours for the: (1) Screener and Consent Process, (2) Parent Baseline Questionnaire, (3) Media Tracking Screener, and (4) three waves of Media Tracking

Questionnaires are no longer needed or requested. In addition, we have completed the baseline and first wave of followup data collection for Cohort 2 of the General Market campaign evaluation.

The new estimated burden for this collection is 25,707 responses and 7,327 hours. This is a decrease of 117,120

responses and 21,010 hours from the current approved information collection.

Dated: August 26, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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