

Data (OMB #0970-0389; expiration 6/30/2022). There are minor updates to the existing Form 1.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 511(h)(2)(A) of Title V of the Social Security Act

created the MIECHV Program and authorizes the Secretary of HHS to award grants to Indian tribes (or a consortium of Indian tribes), tribal organizations, or urban Indian organizations to conduct an early childhood home visiting program. The legislation set aside 3 percent of the total MIECHV program appropriation for grants to tribal entities. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to states and jurisdictions and include conducting a needs assessment and establishing quantifiable, measurable benchmarks. ACF’s OCC, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau, awards grants for the Tribal MIECHV Program. The Tribal MIECHV grant awards support 5-year cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally relevant, evidence-based home visiting programs in at-risk tribal communities; and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

In Year 1 of the cooperative agreement, grantees must (1) conduct a comprehensive community needs and readiness assessment, and (2) develop a plan to respond to identified needs. Following each year that Tribal MIECHV grantees implement home visiting services, they must submit Form 1: Demographic and Service Utilization Data. The Form 1 data are used to help ACF better understand the population receiving services from Tribal MIECHV grantees and the degree to which they are using services, as well as better understand the Tribal MIECHV workforce. Overall, this information collection will provide valuable information to HHS that will guide understanding of the Tribal MIECHV Program and the provision of technical assistance to Tribal MIECHV Program grantees. Changes from the previous form are minor, including adding a virtual home visit field and revising certain terms and definitions to make reporting on the areas more concise and easier for grantees to report.

Respondents: Tribal MIECHV Program Grantees.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Annual number of responses per respondent | Average burden hours per response | Annual burden hours |
|----------------------------|-----------------------------|---|-----------------------------------|---------------------|
| Tribal MIECHV Form 1 | 23 | 1 | 500 | 11,500 |

Estimated Total Annual Burden Hours: 11,500.

Authority: Title V of the Social Security Act, sections 511(e)(8)(A) and 511(h)(2)(A).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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BILLING CODE 4184-43-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0429]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection aspects of the “Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products.”

DATES: Submit either electronic or written comments on the collection of information by April 4, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 4, 2022. The <https://www.regulations.gov>

electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 4, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2012-D-0429 for “Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you

must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products

OMB Control Number 0910-0731—Extension

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a new tobacco product before it may be introduced or delivered into interstate commerce. To provide assistance with these pathways to market products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate as described in “Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products.” This guidance is intended to assist persons who seek meetings with FDA relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products. The original guidance issued in 2012 was revised for updating and clarity in July 2016.

In the guidance, the Agency discusses, among other things:

- What information FDA recommends persons include in a meeting request;
- How and when to submit a request; and
- What information FDA recommends persons submit prior to a meeting.

This guidance describes two collections of information: (1) The submission of a meeting request containing certain information and (2) the submission of an information package in advance of the meeting. The purpose of this proposed information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an effective and efficient manner. FDA issued this guidance and the revisions consistent with FDA’s good guidance practices regulations (21 CFR 10.115).

Meeting Requests: The guidance sets forth FDA’s recommendations for materials to be included in a request for a meeting with FDA to discuss the research and development of tobacco products. In the guidance, FDA recommends that the following

information be included in the meeting request:

1. Product name
2. FDA-assigned Submission Tracking Number(s) of prior submissions (e.g., premarket applications, meeting requests) for the product and relevant product version(s) (if applicable);
3. Product category (e.g., cigarettes, smokeless tobacco) (if applicable);
4. Product use (indicate for consumer use or for further manufacturing);
5. Contact information for the authorized point of contact for the company requesting the meeting;
6. The topic of the meeting being requested (e.g., a new tobacco product application, an application for permission to market a modified risk tobacco product, or investigational use of a new tobacco product);
7. A brief statement of the purpose of the meeting, which could include a discussion of the types of studies or data to be discussed at the meeting, the general nature of the primary questions to be asked, and where the meeting fits in the overall product development plans;
8. A preliminary list of the specific objectives/outcomes expected from the meeting;
9. A preliminary proposed agenda, including an estimate of the time needed and a designated speaker for each agenda item;
10. A preliminary list of specific critical questions, grouped by discipline (e.g., chemistry, clinical, nonclinical);
11. A list of all individuals who will attend the meeting on behalf of the tobacco product manufacturer, importer,

researcher, or investigator, including titles and responsibilities;
 12. The date on which the meeting information package will be received by FDA; and

13. Suggested format of the meeting (e.g., conference call, in-person meeting at FDA offices, video conference, or written response) and suggested dates and times for the meeting. Meetings are usually scheduled for 1 hour. FDA is proposing a meeting request include the FDA-assigned submission tracking numbers of relevant product version(s), if applicable, to allow for FDA to reference such information to better assess and respond to the issues and questions raised in the meeting request.

This information will be used by the Agency to: (1) Determine the utility of the meeting, (2) identify Agency staff necessary to discuss proposed agenda items, and (3) schedule the meeting.

Meeting Information Packages: An individual submitting a meeting information package to FDA in advance of a meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the individual or FDA to be discussed at the meeting. As stated in the guidance, FDA recommends that meeting information packages generally include updates of information that was submitted with the meeting request and, as applicable:

1. Product composition and design data summary;
2. Manufacturing and process control data summary;
3. Nonclinical data summary;
4. Clinical data summary;

5. Behavioral and product use data summary;
6. User and nonuser perception data summary; and
7. Investigational plans for studies and surveillance of the tobacco product, including a summary of proposed study protocols containing the following information (as applicable):
 - a. Study objective(s);
 - b. Study hypotheses;
 - c. Study design;
 - d. Study population (inclusion/exclusion criteria, comparison group(s));
 - e. Human subject protection information, including Institutional Review Board information;
 - f. Primary and secondary endpoints (definition and success criteria);
 - g. Sample size calculation;
 - h. Data collection procedures;
 - i. Duration of follow up and baseline and follow up assessments, and
 - j. Data analysis plan(s).

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. In the Agency's experience, reviewing such information is critical to achieving a productive meeting. If the information package was previously submitted in the meeting request, it should be revised, as applicable, so that the information reflects the most current and accurate information available.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|--------------|
| Meeting Requests | | | | | |
| Combining and Sending Meeting Request Letters for Manufacturers, Importers, and Researchers | 60 | 1 | 60 | 10 | 600 |
| Meeting Information Packages | | | | | |
| Combining and Submitting Meeting Information Packages for Manufacturers, Importers, and Researchers | 60 | 1 | 60 | 18 | 1,080 |
| Total | | | | | 1,680 |

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

FDA's estimate of the number of respondents for meeting requests in table 1 is based on the number of meeting requests received and projected over the next 3 years. FDA estimates that 60 preapplication meetings will be requested.

The hours per response for combining and sending meeting request letters are estimated at 10 hours each, and the total burden hours for meeting requests are expected to be 600 hours. Based on FDA's experience, the Agency expects it will take respondents this amount of time to prepare, gather, copy, and

submit brief statements about the product and a description of the purpose and details of the meeting.

FDA estimates that 60 respondents will compile meeting information packages and submit to FDA at 18 hours per response. Based on FDA's experience, the Agency expects that it

will take respondents, collectively, 1,080 hours to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information, including identifying prior FDA submissions for the product or relevant versions of the product, that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is estimated to be 1,680 hours (600 hours to prepare and submit meeting requests and 1,080 hours to prepare and submit information packages). Our estimated burden for the information collection reflects an overall decrease of 644 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years and our projections for the next 3 years.

Dated: January 25, 2022.
Lauren K. Roth,
Associate Commissioner for Policy.
 [FR Doc. 2022-02055 Filed 2-1-22; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0079]

Hikma Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of 29 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 29 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug

products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 4, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, *Kimberly.Lehrfeld@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

| Application No. | Drug | Applicant |
|-----------------|--|--|
| NDA 006134 | Dolophine (methadone hydrochloride (HCl)) Tablets, 5 milligrams (mg), and 10 mg. Dolophine (methadone HCl) Syrup, 10 mg/30 milliliter (mL). | Hikma Pharmaceuticals USA, Inc., 1809 Wilson Rd., Columbus, OH 43228. |
| NDA 006882 | Phisohex (hexachlorophene) Emulsion, 3% | Sanofi-aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807. |
| NDA 009818 | Kemadrin (procyclidine HCl) Tablets, 2 mg, and 5 mg | Monarch Pharmaceuticals, LLC, c/o Pfizer, Inc., 235 East 42nd St., New York, NY 10017. |
| NDA 012301 | Librium (chlordiazepoxide HCl), Injection, 100 mg/ampule. | Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807. |
| NDA 013416 | Norgesic (orphenadrine citrate, aspirin, and caffeine) Tablets, 25 mg/385 mg/30 mg. Norgesic Forte (orphenadrine citrate, aspirin, and caffeine) Tablets, 50 mg/770 mg/60 mg. | Bausch Health US, LLC. |
| NDA 014228 | Spandin (aspirin and sodium salicylate) Time-released Tablets, 7.5 grains/2.5 grains. | Abbott Healthcare Pvt. Ltd., c/o G&L Scientific, Independence Blvd., 4th Floor, Warren, NJ 07059. |
| NDA 016194 | Talwin (pentazocine lactate) Injection, equivalent to (EQ) 30 mg base/mL. | Hospira Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045. |
| NDA 016418 | Inderal (propranolol HCl) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, 80 mg, and 90 mg. | Wyeth Pharmaceuticals LLC, 235 E. 42nd St., New York, NY 10017. |
| NDA 016704 | Resectisol (mannitol) Irrigation Solution, 5 grams (g)/100 mL. | B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109. |
| NDA 016762 | Inderal (propranolol HCl) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, and 80 mg. | Wyeth Pharmaceuticals LLC. |
| NDA 016954 | Micronor (norethindrone) Tablets, 0.35 mg | Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560. |
| NDA 017013 | Sodium Chloride Injection, 20 g/100 mL | Abbott Healthcare Pvt. Ltd., c/o G&L Scientific. |
| NDA 017683 | Inderal (propranolol HCl) Tablets, 10 mg, 20 mg, 40 mg, 60 mg, and 80 mg. | Wyeth Pharmaceuticals LLC. |
| NDA 018423 | Hibiclens (chlorhexidine gluconate) Sponge, 4% | Mölnlycke Health Care, 5445 Triangle Pkwy., Suite 400, Peachtree Corners, GA 30092. |
| NDA 018703 | Zantac (ranitidine HCl) Tablets, EQ 150 mg base, and EQ 300 mg base. | GlaxoSmithKline Intellectual Property Ltd. England, c/o GlaxoSmithKline, 5 Crescent Dr., Philadelphia, PA 19112. |
| NDA 019387 | Profenal (suprofen) Ophthalmic Solution, 1% | Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134-2099. |
| NDA 019530 | Ucephan (sodium benzoate and sodium phenylacetate) Solution, 100 mg/mL; 100 mg/mL. | B. Braun Medical Inc. |
| NDA 019675 | Zantac (ranitidine HCl) Syrup, EQ 15 mg base/mL | GlaxoSmithKline Intellectual Property Ltd. England, c/o GlaxoSmithKline. |
| NDA 019814 | Betagan (levobunolol HCl) Ophthalmic Solution, 0.25% | Allergan, Inc. |
| NDA 019927 | Nizoral (ketoconazole) Shampoo, 2% | Janssen Pharmaceuticals, Inc. |