compounded drugs needed by hospitals, clinics, and other providers. Five years since its creation, this domestic industry is still relatively small and is experiencing growth and market challenges. In addition, FDA continues to find concerning quality and safety problems during inspections.

To help this industry meet its intended function, FDA intends to engage in several initiatives to address challenges and support compliance and advancement. One initiative includes conducting in-depth research to better understand challenges and opportunities encountered by the outsourcing facility sector in a number of different areas. These include: Operational barriers and opportunities related to the outsourcing facility market and business viability; knowledge and operational barriers and opportunities related to compliance with federal policies and good quality drug production; and barriers and opportunities related to outsourcing facility interactions with FDA.

The results of this research will be used by FDA to develop a comprehensive understanding of the outsourcing facility sector, its challenges, and opportunities for advancement. The information will be essential to help identify knowledge and information gaps, operational barriers, and views on interactions with FDA. The research results will inform FDA's future approaches to communication, education, training, and other engagement with outsourcing facilities to address challenges and support advancement.

Researchers will engage pharmacists, staff, and management from outsourcing facilities and similar compounding businesses. Researchers may use surveys, interviews, and focus groups to obtain information concerning challenges and opportunities encountered by outsourcing facilities. Within this context, the following questions or similar, related questions may be posed:

1. What financial and operational considerations inform outsourcing facility operational and business model decisions?
2. What factors impact the development of a sustainable outsourcing facility business?
3. What financial and operational considerations inform outsourcing facility product decisions?
4. Do outsourcing facilities understand the federal legislative and regulatory policies that apply to them? What, if any, knowledge gaps need to be addressed?
5. What challenges do outsourcing facilities face when implementing federal Current Good Manufacturing Practice (CGMP) requirements?
6. How do outsourcing facilities implement quality practices at their facilities?
7. How is CGMP and quality expertise developed by outsourcing facilities? How do they obtain this knowledge, and what training do they need?
8. What are the economic consequences of CGMP non-compliance/product failures for outsourcing facilities?
9. What are outsourcing facility management and staff views on current interactions with FDA? How do they want the interactions to change?
10. What are outsourcing facilities' understanding of how to engage with FDA during and following an inspection?

In the **Federal Register** of July 29, 2019 (84 FR 36609), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, one was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document. The other comment included a number of suggested questions to expand upon the questions posed in the 60-day notice and therefore can be considered ways to enhance the quality, utility, and clarity of the information to be collected. While the questions will not be included verbatim in our survey instrument, FDA will give the questions due consideration as the Agency proceeds with this study.

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
Surveys, focus groups, and interviews	300	2	600	1	600

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

We base our estimate of the average burden per response on review activities familiar to the Agency.

Dated: December 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27053 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidance for Cocaine Hydrochloride; Nasal Solution; New Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a new draft guidance for industry, entitled ''Draft Guidance for Cocaine Hydrochloride.'' The new draft guidance, when finalized, will provide product-specific recommendations on, among other things, the information and data needed to demonstrate bioequivalence (BE) to support abbreviated new drug applications (ANDAs) for a cocaine hydrochloride nasal solution.

DATES: Submit either electronic or written comments on the draft guidance by February 14, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments as follows:

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–2007–D–0369 for ''Draft Guidance for Cocaine Hydrochloride.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Mara Miller, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4709C, Silver Spring, MD 20993–0002, 301–796–0683.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a new draft guidance on a generic cocaine hydrochloride nasal solution.

FDA initially approved new drug application 209963 GOPRELTO (cocaine hydrochloride) nasal solution in December 2017. We are now issuing a new draft guidance for industry on a generic cocaine hydrochloride nasal solution (''Draft Guidance on Cocaine Hydrochloride'').

The new draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The new draft guidance, when finalized, will represent the current thinking of FDA on the information and data to demonstrate BE to support ANDAs for cocaine hydrochloride nasal solution. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26971 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center of Drug Evaluation and Research (CDER) has modified its structure. This new organizational structure was approved