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Instructions: All submissions received must include the Docket No. FDA–2007–D–0369 for ''Draft Guidance for Cocaine Hydrochloride.''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

by the Secretary of Health and Human Services on September 25, 2019.

FOR FURTHER INFORMATION CONTACT: Edwin Echegoyen, Acting Director, Office of Management/Executive Officer, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, Silver Spring, MD 20993, 301–796–3300.

I. Summary

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56606, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; 74 FR 41713, August 18, 2009; and 76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Center of Drug Evaluation and Research.

This reorganization consists of the following Offices: Office of New Drugs (OND), Office of Translational Science (OTS), and Office of Pharmaceutical Quality (OPQ) within the Center for Drug Evaluation and Research and revises their functional statements. The proposed organizational changes align with the ReImagine HHS strategic shift moving to the 21st century: Maximizing Talent, Integrated Assessments, Benefit Risk Monitoring, and Leveraging the Power of Data. CDER will meet the definition of Maximizing Talent by focusing on growing our scientific leadership. This will result in clearly designed pathways to regulatory approval and enhanced emphasis on multidisciplinary teams. The proposed reorganization will integrate assessments to critically, collaboratively, and consistently assess whether information in submissions meets statutory and regulatory requirements. OND, OPQ, and OTS will establish Benefit-Risk Monitoring to unify the post-market safety surveillance framework leading to operational excellence by aligning the therapeutic focus. Each of these offices will incorporate Leveraging the Power of Data to provide access to analytical tools and systems to help the reviewers evaluate and interpret submitted data, thereby improving and streamlining the processes which will impact the critical analyses leading to efficiencies and effectiveness in CDER's scientific regulatory review.

Under Part D, FDA, the Center for Drug Evaluation and Research (CDER) has been restructured as follows:

Standard Administrative Codes (SAC). ORGANIZATION—CDER is headed by the Director and includes the following organizational units:

Office of Regulatory Policy (SAC)
Office of Management (SAC)
Office of Communications (SAC)
Office of Compliance (SAC)
Office of Manufacturing Quality (SAC)
Office of Unapproved Drugs and Labeling Compliance (SAC)
Office of Scientific Investigations (SAC)
Office of Program and Regulatory Operations (SAC)
Office of Medical Policy (SAC)
Office of Prescription Drug Promotion (SAC)
Office of Medical Policy Initiatives (SAC)
Office of Translational Sciences (SAC)
Office of Biostatistics (SAC)
Office of Clinical Pharmacology (SAC)
Office of Computational Science (SAC)
Office of Study Integrity and Surveillance (SAC)
Office of Administrative Operations (SAC)
Office of Executive Programs (SAC)
Office of Surveillance and Epidemiology (SAC)
Office of Medication Error Prevention and Risk Management (SAC)
Office of Pharmacovigilance and Epidemiology (SAC)
Office of New Drugs (SAC)
Office of Administrative Operations (SAC)
Office of Cardiology, Hematology, Endocrinology & Nephrology (SAC)
Office of Drug Evaluation Science (SAC)
Office of Immunology & Inflammation (SAC)
Office of Infectious Diseases (SAC)
Office of Neuroscience (SAC)
Office of New Drug Policy (SAC)
Office of Nonprescription Drugs (SAC)
Office of Oncologic Diseases (SAC)
Office of Program Operations (SAC)
Office of Rare Diseases, Pediatrics, Urology & Reproductive Medicine (SAC)
Office of Regulatory Operations (SAC)
Office of Specialty Medicine (SAC)
Office of Therapeutic Biologics and Biosimilars (SAC)
Office of Strategic Programs (SAC)
Office of Program and Strategic Analysis (SAC)
Office of Business Informatics (SAC)
Office of Generic Drugs (SAC)
Office of Research Standards (SAC)
Office of Bioequivalence (SAC)
Office of Generic Drug Policy (SAC)
Office of Regulatory Operations (SAC)
Office of Pharmaceutical Quality (SAC)
Office of Administrative Operations (SAC)
Office of Biotechnology Products (SAC)
Office of Lifecycle Drug Products (SAC)
Office of New Drug Products (SAC)
Office of Pharmaceutical Manufacturing Assessment (SAC)
Office of Policy for Pharmaceutical Quality (SAC)
Office of Program and Regulatory Operations (SAC)
Office of Quality Surveillance (SAC)
Office of Testing and Research (SAC)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete SMG can find it on FDA's website at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Alex M. Azar, II,

Secretary.

[FR Doc. 2019–26952 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE (P50) III Review.

Date: January 29–30, 2020.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.