recommends that 3P Review Organizations establish a recordkeeping system for tracking the submission of those complaints and how those complaints were resolved, or attempted to be resolved. Therefore, we have added an IC for ''Recordkeeping system regarding complaints.'' Based on our experience with the program and the recommendations in the guidance, we estimate the average burden per recordkeeping to be 2 hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews [3]	7	21	147	10	1,470
Records regarding qualifications to receive FDA recognition as a 3P Review Organization [4]	7	1	7	1	7
Recordkeeping system regarding complaints [4]	7	1	7	2	14
Total					1,491

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

We revised our estimates for OMB control number 0910–0375 by adding new ICs, changing the title of the ICR, and adjusting the existing ICs based on current trends. Despite the addition of new ICs, the estimated burden reflects an overall decrease of 5,581 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

The draft guidance also refers to previously approved ICs found in FDA regulations. The ICs in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the ICs regarding 3P Review of medical devices under FDAMA have been approved under OMB control number 0910–0375; the ICs for the device appeals processes have been approved under OMB control number 0910–0738; the ICs in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: September 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19992 Filed 9–13–18; 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 Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on the draft guidance by November 13, 2018 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 on any guidance at any time 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 ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' Received comments 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.

- 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 guidances 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 documents.

FOR FURTHER INFORMATION CONTACT: Wendy Good, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 240–402–9682.

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'' that 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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on July 20, 2018. This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of a new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Abemaciclib
Albuterol sulfate
Allopurinol; Lesinurad
Amantadine hydrochloride
Amphetamine aspartate; Amphetamine sulfate; Dextroamphetamine saccharate; Dextroamphetamine sulfate
Azelaic acid
Benznidazole
Brigatinib
Brimonidine tartrate; Timolol maleate
Chlorzoxazone
Ciprofloxacin hydrochloride
Dapagliflozin propanediol; Saxagliptin hydrochloride
Delafloxacin meglumine
Desonide
Deutetrabenazine
Diazepam
Efinaconazole
Enasidenib mesylate
Glecaprevir; Pibrentasvir
Ibuprofen; Pseudoephedrine hydrochloride
Ivermectin
Lamotrigine
Luliconazole
Midostaurin
Miltefosine
Morphine sulfate
Neratinib maleate
Olaparib
Olive oil; Soybean oil
Oxycodone hydrochloride
Penciclovir
Perflutren
Pilocarpine hydrochloride
Pitavastatin magnesium
Pitavastatin sodium
Pregabalin
Secnidazole
Sofosbuvir; Velpatasvir; Voxilaprevir
Spironolactone
Sulfur hexafluoride lipid-type a microspheres
Talc
Tavaborole

III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Acetazolamide
Chlorpromazine hydrochloride
Doxorubicin hydrochloride
Morphine sulfate
Nicotine polacrilex (multiple Reference Listed Drugs)
Nisoldipine
Oxycodone
Raltegravir potassium
Tacrolimus (multiple strengths)

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

IV. Electronic Access

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

Dated: September 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20018 Filed 9–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting conducted as a telephone conference call. This call will be open to the public. Preregistration is required for both public participation and comment. Any individual who wishes to participate in the call should email *OMH-ACMH@hhs.gov* by October 11, 2018. Instructions regarding participating in the call and how to provide verbal public comments will be given at the time of preregistration. Information about the meeting is available from the designated contact and will be posted on the website for the Office of Minority Health (OMH), *www.minorityhealth.hhs.gov.* Information about ACMH activities can be found on the OMH website under the heading *About OMH.*

DATES: The conference call will be held on October 16, 2018, 1 p.m. to 3 p.m. EST.

ADDRESSES: Instructions regarding participating in the call will be given at the time of preregistration.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer, Advisory Committee on Minority Health, Office of Minority Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852. Phone: 240–453–8222; fax: 240–453–8223; email *OMH-ACMH@hhs.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105–392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on improving the health of each racial and ethnic minority group and on the development of goals and specific program activities of the OMH.

The topics to be discussed during the teleconference include finalizing recommendations regarding innovative systems of care, barriers to effective data collection, and primary prevention related serious mental illness; discussing the framework and speakers for the following disparities-themed report that will include recommendations; and discussing the agenda for the next meeting. The recommendations will be given to the Deputy Assistant Secretary for Minority Health.

This call will be limited to 125 participants. The OMH will make every effort to accommodate persons with special needs. Individuals who have special needs for which special accommodations may be required should contact Professional and Scientific Associates at (703) 234–1700 and reference this meeting. Requests for special accommodations should be made at least ten (10) business days prior to the meeting.

Members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to two minutes per speaker during the time allotted. Individuals who would like to submit written statements should email, mail, or fax their comments to the designated contact at least seven (7) business days prior to the meeting.

Any members of the public who wish to have electronic or printed material distributed to ACMH members should email *OMH-ACMH@hhs.gov* or mail their materials to the Designated Federal Officer, ACMH, Tower Building, 1101 Wootton Parkway, Suite 600, Rockville, Maryland 20852, prior to close of business on October 11, 2018.

Dated: September 5, 2018.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2018–20040 Filed 9–13–18; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0801]

Certificate of Alternative Compliance for the TUG JUDY MORAN Hull 123

AGENCY: Coast Guard, DHS.

ACTION: Notification of issuance of a certificate of alternative compliance.

SUMMARY: The Coast Guard announces that the U. S. Coast Guard First District Prevention Division has issued a certificate of alternative compliance from the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), for the TUG JUDY MORAN, Hull 123. We are issuing this notice because its publication is required by statute. Due to the construction and placement of the vessel's side lights and stern lights, TUG JUDY MORAN cannot fully comply with the light, shape, or sound signal provisions of the 72 COLREGS without interfering with the vessel's design and construction. This notification of issuance of a certificate of alternative compliance promotes the Coast Guard's marine safety mission.

DATES: The Certificate of Alternative Compliance was issued on 26 July, 2018.

FOR FURTHER INFORMATION CONTACT: For information or questions about this notice call or email Mr. Kevin Miller, First District Towing Vessel/Barge Safety Specialist, U.S. Coast Guard; telephone (617) 223–8272, email *Kevin.L.Miller2@uscg.mil.*

SUPPLEMENTARY INFORMATION:

The United States is signatory to the International Maritime Organization's International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as amended. The special construction or purpose of some vessels makes them unable to comply with the light, shape, or sound signal provisions of the 72 COLREGS. Under statutory law, however, specified 72 COLREGS provisions are not applicable to a vessel of special construction or purpose if the Coast Guard determines that the vessel cannot comply fully with those requirements without interfering with the special function of the vessel.[1]

The owner, builder, operator, or agent of a special construction or purpose vessel may apply to the Coast Guard District Office in which the vessel is being built or operated for a determination that compliance with alternative requirements is justified,[2] and the Chief of the Prevention Division would then issue the applicant a certificate of alternative compliance (COAC) if he or she determines that the vessel cannot comply fully with 72 COLREGS light, shape, and sound signal provisions without interference with the vessel's special function.[3] If the Coast Guard issues a COAC, it must publish notice of this action in the **Federal Register**.[4]

[1] 33 U.S.C. 1605.

[2] 33 CFR 81.5.

[3] 33 CFR 81.9.

[4] 33 U.S.C. 1605(c) and 33 CFR 81.18.