appropriate) through existing mechanisms. See, for example, FDA draft guidances entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products and Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products'' (once final, these guidance documents will represent FDA's current thinking on these topics) to improve the likelihood that a list of agreed-upon ECs can be reached prior to application approval. Although FDA's Center for Biologics Evaluation and Research (CBER) is not participating in this pilot, CBER intends to leverage CDER's experience from the pilot as CBER assesses explicit ECs in future submissions.

III. Requests To Participate

Parties who have an interest in participating in this Established Conditions Pilot Program and who plan to propose explicit ECs in an upcoming marketing application should submit a written request to the *CDER-OPQ-Inquiries@fda.hhs.gov* mailbox. The request should specify the request to participate in the Established Conditions Pilot Program.

The request should also include the following items:

1. The contact person's name, company name, and company contact information.
2. The proposed application type (NDA, ANDA, BLA; original or supplement).
3. The established name of the proposed product and a brief description (*e.g.,* dosage form, indication).
4. Plans for any pre-NDA, pre-BLA, or pre-ANDA meetings to take place prior to application submission. Requests for such meetings should follow previously established procedures as outlined in relevant guidance documents.
5. Expected timing for submission of the application. The submission should be planned for receipt by FDA no later than July 1, 2019.
6. Acknowledgement that participation in the pilot program may be discontinued if the manufacturing facilities named in the application are not in a state of compliance with CGMP at the time of the application submission.

We intend to accept nine requests that meet the criteria above and represent a variety of application types, as Agency resources allow. FDA expects to notify companies of its decision regarding acceptance into the pilot program in writing within 60 days of receipt of the request. Although incomplete and/or unclear requests will generally be denied, FDA may contact the applicant to request additional information.

FDA intends to accept requests to participate starting on the date of publication of this notice.

IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

The collections of information in 21 CFR part 314 for submitting NDAs and ANDAs have been approved under OMB control number 0910–0001, and the collections of information in 21 CFR part 601 for submitting BLAs has been approved under OMB control number 0910–0338.

FDA also has OMB approval under control number 0910–0429 for submissions under the guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants,'' and under the guidance for industry ''Controlled Correspondence Related to Generic Drug Development'' (OMB control number 0910–0797).

V. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are also available electronically at *https://www.regulations.gov.* FDA verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA draft guidance for industry entitled ''Established Conditions: Reportable CMC Changes for Approved Drug and Biologic Products'' (May 2015), available at *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm448638.pdf.*
2. FDA draft guidance for industry entitled ''ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management'' (May 2018), available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609205.pdf.*
3. FDA draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants for PDUFA Products'' (December 2017), available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM590547.pdf.*
4. FDA draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products'' (June 2018), available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609662.pdf.*
5. FDA draft guidance for industry entitled ''Controlled Correspondence Related to Generic Drug Development'' (November 2017), available at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM583436.pdf.*

Dated: February 11, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02364 Filed 2–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0482]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With New Animal Drug Applications and Veterinary Master Files

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 collection of information associated with new animal drug applications.

DATES: Submit either electronic or written comments on the collection of information by April 16, 2019.

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 16, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 16, 2019. 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–2019–N–0482 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated with New Animal Drug Applications and Veterinary Master Files.'' 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.

- 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.

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. 3501–3520), 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.

Reporting Associated With New Animal Drug Applications (NADA) and Veterinary Master Files—21 CFR 514.1, 514.4, 514.5, 514.6, 514.8, 514.11, and 558.5

OMB Control Number 0910–0032—Extension

Under section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(b)(1)), any person may file a new animal drug application (NADA) seeking our approval to legally market a new animal drug. Section 512(b)(1) sets forth the information required to be submitted in a NADA. Sections 514.1, 514.4, 514.6, 514.8, and 514.11 of our regulations (21 CFR 514.1, 514.4, 514.6, 514.8, and 514.11) further specify the information that the NADA must contain. The application must include safety and effectiveness data, proposed labeling, product manufacturing information, and where necessary, complete information on food safety (including microbial food safety) and any methods used to determine residues of drug chemicals in edible tissue from food producing animals. FDA Guidance #152 outlines a risk assessment approach for evaluating the microbial food safety of antimicrobial new animal drugs. We request that applicants utilize Form FDA 356V, as appropriate, to ensure efficient and accurate processing of information to support new animal drug approval.

Under section 512(b)(3) of the FD&C Act, any person intending to file a NADA or supplemental NADA or a

request for an investigational exemption under section 512(j) of the FD&C Act is entitled to one or more conferences with us prior to making a submission. Section 514.5 of our regulations (21 CFR 514.5) describes the procedures for requesting, conducting, and documenting presubmission conferences. We have found that these meetings have increased the efficiency of the drug development and drug review processes. We encourage sponsors to submit data for review at the most appropriate and productive times in the drug development process. Rather than submitting all data for review as part of a complete application, we have found that the submission of data supporting discrete technical sections during the investigational phase of the new animal drug is the most appropriate and productive. This ''phased review'' of data submissions has created efficiencies for both us and the animal pharmaceutical industry.

Additionally, we have found that various uses of veterinary master files have increased the efficiency of the drug development and drug review processes for both us and the animal pharmaceutical industry. A veterinary master file is a repository for submission to FDA's Center for Veterinary Medicine of confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more veterinary drugs. The benefits of veterinary master files include confidential exchange of information with FDA, a process for reporting information outside of a NADA or an investigational new animal drug (INAD) file, as well as an opportunity for increased communication with FDA during early stages of product development. Respondents may choose to use veterinary master files to provide and organize confidential detailed information to the Agency. A holder of a veterinary master file may also authorize other parties to reference information in the veterinary master file without disclosing information in the file to those parties. Veterinary master files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden. Veterinary master files are already used by the animal pharmaceutical industry in support of information being submitted for NADAs, abbreviated new animal drug applications (ANADAs), INAD files, and generic investigational new animal drug (JINAD) files. In previous information collection requests, we have included the time necessary to compile and submit such information to veterinary master files within the burden estimates provided for applications and amended applications (for NADAs and INAD files) and abbreviated applications and amended abbreviated applications (for ANADAs and JINAD files), respectively. We are now combining the time necessary to compile and submit such information to veterinary master files within the burden estimates provided in this collection of information.

We are also developing new approaches to permit more complex uses of veterinary master files to facilitate the development of animal drug products. We expect respondents will want to use veterinary master files to submit information to us for review and consultation during all phases of animal drug product development (including product development that precedes the establishment of an INAD file or the submission of a NADA). This information could include information about processes, facilities, or articles used in the manufacturing, processing, packaging, and storing of veterinary drugs and drug substances. Information submitted to FDA through a veterinary master file could also include drug characterization, methods, protocols, or other relevant information. In this request for OMB review, we seek approval of an increased use of veterinary master files by respondents to submit additional information to us for review and consultation during all phases of animal drug product development (including product development that precedes the establishment of an INAD file or the submission of a NADA). To account for an expected increase in reporting burden hours associated with the increased use of veterinary master files by respondents, we are separately estimating in table 1, row 10, the burden of the use of veterinary master files during all phases of product development (including product development that precedes the establishment of an INAD file or the submission of a NADA).

Finally, § 558.5(i) of our regulations (21 CFR 558.5(i)) describes the procedure for requesting a waiver of the labeling requirements of § 558.5(h) in the event that there is evidence to indicate that it is unlikely a new animal drug would be used in the manufacture of a liquid medicated feed.

The reporting associated with NADAs and related submissions is necessary to ensure that new animal drugs are in compliance with section 512(b)(1) of the FD&C Act. We use the information collected to review the data, labeling, and manufacturing controls and procedures to evaluate the safety and effectiveness of the proposed new animal drug.

Description of Respondents: Respondents include persons developing, manufacturing, and/or researching new animal drugs.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.1 and 514.6; applications and amended applications ..	182	0.05	9	212	1,908
514.1(b)(8) and 514.8(c)(1); [2] evidence to establish safety and effectiveness	182	0.10	18	90	1,620
514.5(b), (d), (f); requesting presubmission conferences ...	182	0.49	89	50	4,450
514.8(b); manufacturing changes to an approved application	182	1.40	255	35	8,925
514.8(c)(1); labeling and other changes to an approved application	182	0.05	9	71	639
514.8(c)(2) and (3); labeling and other changes to an approved application	182	0.43	78	20	1,560
514.11; submission of data, studies, and other information	182	0.09	16	1	16
558.5(i); requirements for liquid medicated feed	182	0.01	2	5	10
Form FDA 356V	182	2.92	531	5	2,655

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Use of veterinary master files during all phases of product development (including product development that precedes the establishment of an INAD file or the submission of a NADA)	15	1	15	20	300
Total			1,022		22,083

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] NADAs and supplements regarding antimicrobial animal drugs that use a recommended approach to assessing antimicrobial concerns as part of the overall preapproval safety evaluation.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our previous estimates. However, as discussed, we have separately estimated the burden of the ''Use of veterinary master files during all phases of product development (including product development that precedes the establishment of an INAD file or the submission of an NADA)'' in table 1, row 10. We base our estimate of the total annual responses for the use of veterinary master files on such uses initiated during calendar year 2018. We base our estimate of the hours per response upon our experience with the respondents' use of veterinary master files. We estimate that the time it takes to compile information and submit it to a veterinary master file will vary from 1 to 50 hours, depending on the complexity of the information; therefore, we are estimating on average the burden per response to be 20 hours. Accordingly, we report an additional 300 burden hours and 15 total annual responses in row 10. We are also correcting several rounding errors that were made in our last request for OMB approval. Correcting these rounding errors reduces our previously reported total burden hours and total responses. Thus, our estimated burden for the information collection reflects a net overall increase of 124 hours and a corresponding increase of 14 responses.

Dated: February 11, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–02479 Filed 2–14–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration (HRSA), the Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: HHS is hereby giving notice that the Advisory Council on Blood Stem Cell Transplantation (ACBSCT) has been renewed. The effective date of the renewed charter is February 19, 2019.

FOR FURTHER INFORMATION CONTACT: Robert Walsh, Executive Secretary, ACBSCT, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857. Phone: 301–443–6839; email: *rwalsh@hrsa.gov.*

SUPPLEMENTARY INFORMATION: Relevant statutes are Public Law 109–129 as amended by Public Law 111–264; 42 U.S.C. 274k; and Section 379 of the Public Health Service Act. The Council is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. appendix 2), which sets forth standards for the formation and use of advisory committees.

ACBSCT advises and makes recommendations to the Secretary of Health and Human Services (Secretary) on matters related to the activities of the C.W. Bill Young Cell Transplantation Program and the National Cord Blood Inventory Program. One of its principal functions shall be to provide consolidated, comprehensive sources of expert, unbiased analysis and recommendations to the Secretary on the latest advances in the science of blood stem cell transplantation.

ACBSCT may meet up to three times during the fiscal year. The charter renewal for ACBSCT was approved on February 7, 2019. The filing date is February 19, 2019. Renewal of the ACBSCT charter authorizes the Council to operate until February 19, 2021.

A copy of the ACBSCT charter is available on the ACBSCT website at: *https://bloodcell.transplant.hrsa.gov/about/advisory_council/index.html.* A copy of the charter can also be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/.*

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–02399 Filed 2–14–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Retail Pharmacy Interest in Utilization of Innovative Educational Technology To Increase Human Papillomavirus (HPV) Vaccination Rates in Rural Areas

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This request for information (RFI) is issued for informational and planning purposes only. This RFI is not a solicitation; nor does it commit the Department of Health and Human Services (HHS) to issue a solicitation, make any award, or pay any costs associated with responding to this announcement.

The RFI is being issued by the National Vaccine Program Office (NVPO) of the U.S. Department of Health and Human Services. The NVPO is located in the Office of the Assistant Secretary for Health (ASH), Office of the Secretary (OS), U.S. Department of Health and Human Services (HHS). The NVPO provides strategic leadership and