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.

In the **Federal Register** of February 15, 2019 (84 FR 4479), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates 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 & 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) & (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
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)	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 pre-approval 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, line 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, our estimated burden for the information collection reflects an overall increase of 124 hours and a corresponding increase of 14 responses.

Dated: June 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13430 Filed 6–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4534]

Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Reducing Microbial Food Safety Hazards in the Production of Seed for

Sprouting.'' The draft guidance document, when finalized, will make the sprout seed industry (seed growers, conditioners, packers, holders, suppliers, and distributors) aware of FDA's serious concern with the continuing outbreaks of foodborne illness associated with the consumption of raw and lightly-cooked sprouts and provide FDA's recommendations to firms throughout the production chain of seed for sprouting.

DATES: Submit either electronic or written comments on the draft guidance by August 26, 2019 to ensure that FDA considers your comment on the 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–2018–D–4534 for ''Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting: Draft Guidance 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.'' We will review this copy, including the claimed confidential information, in our 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 Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Patricia Homola, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1700.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Reducing Microbial Food Safety Hazards in the Production of Seed for Sprouting.'' The draft guidance, when finalized, will make the sprout seed industry (seed growers, conditioners, packers, holders, suppliers, and distributors) aware of our serious concern with the continuing outbreaks of foodborne illness associated with the consumption of raw and lightly-cooked sprouts and provide our recommendations to firms throughout the production chain of seed for sprouting. In the development of the draft guidance, we considered three documents related to food safety and hygienic production of seed for sprouting: (1) The Codex Code of Hygienic Practice for Fresh Fruits and Vegetables Annex II, Annex for Sprout Production (Ref. 1); (2) the International Sprout Growers Association—Institute for Food Safety and Health's ''U.S. Sprout Production Best Practices'' (Section 2. Raw Material Sourcing) (Ref. 2); and (3) the European Sprouted Seeds Association (ESSA) Hygiene Guideline for the Production of Sprouts and Seeds for Sprouting (Section 2. Production of Seeds) (Ref. 3). We have incorporated aspects of these documents that are consistent with our laws and regulations, as well as our existing policies.

We are issuing the draft guidance consistent with our good guidance practice regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous

sentence to find the most current version of the guidance.

III. References

The following references are on display at 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; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Codex ''Code of Hygienic Practice for Fresh Fruits and Vegetables,'' CAC/RCP 53–2003, Annex II, Annex for Sprout Production, Revision 2010. Retrieved from *https://www.ifsh.iit.edu/sites/ifsh/files/departments/ssa/pdfs/codex2003_053e.pdf.*

2. International Sprout Growers Association—Institute for Food Safety and Health's ''U.S. Sprout Production Best Practices'' (Section 2. Raw Material Sourcing). Retrieved from *https://www.ifsh.iit.edu/us-sprout-industry-production-best-practices.*

3. Official Journal of the European Union, ''ESSA Hygiene Guideline for the Production of Sprouts and Seeds for Sprouting (2017/(220/03),'' (Section 2. Production of Seeds). Retrieved from *https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52017XX0708(01)&from=EN.*

Dated: June 19, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13433 Filed 6–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

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

ACTION: Notice.

SUMMARY: This notice informs the public of the availability of the complete lists of all geographic areas, population groups, and facilities designated as primary medical care, mental health, and dental health professional shortage areas (HPSAs) as of May 1, 2019. The lists are available on HRSA's HPSAFind website.

ADDRESSES: Complete lists of HPSAs designated as of May 1, 2019, are available on the website at *https://data.hrsa.gov/topics/health-workforce/shortage-areas.* Frequently updated information on HPSAs is available at *https://data.hrsa.gov/tools/shortage-area.* Information on shortage designations is available at *https://bhw.hrsa.gov/shortage-designation.*

FOR FURTHER INFORMATION CONTACT: For further information on the HPSA designations listed on the website or to request additional designation, withdrawal, or reapplication for designation, please contact Janelle D. McCutchen, DHEd, MPH, CHES, Chief, Shortage Designation Branch, Division of Policy and Shortage Designation, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 11W14, Rockville, Maryland 20857, *sdb@hrsa.gov* or phone at (301) 594–5168.

SUPPLEMENTARY INFORMATION:

Background

Section 332 of the Public Health Service (PHS) Act, 42 U.S.C. 254e, provides that the Secretary shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. Section 332 further requires that the Secretary annually publish lists of the designated geographic areas, population groups, and facilities. The lists of HPSAs are to be reviewed at least annually and revised as necessary.

Final regulations (42 CFR part 5) were published in 1980 and include the criteria for designating HPSAs. Criteria were defined for seven health professional types: Primary medical care, dental, psychiatric, vision care, podiatric, pharmacy, and veterinary care. The criteria for correctional facility HPSAs were revised and published on March 2, 1989 (54 FR 8735). The criteria for psychiatric HPSAs were expanded to mental health HPSAs on January 22, 1992 (57 FR 2473). Currently funded PHS Act programs use only the primary medical care, mental health, or dental HPSA designations.

HPSA designation offers potential access to federal assistance. Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps (NHSC) personnel to provide primary medical care, mental health, or dental health services in or to these HPSAs. NHSC health professionals enter into service agreements to serve in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain residency training program grants administered by HRSA's Bureau of Health Workforce (BHW). Other federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare and Medicaid Services, certain qualified providers in geographic area HPSAs are eligible for increased levels of Medicare reimbursement.

Content and Format of Lists

The three lists of designated HPSAs are available on the HRSA Data Warehouse HPSAFind website and include a snapshot of all geographic areas, population groups, and facilities that were designated HPSAs as of May 1, 2019. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the **Federal Register** on July 2, 2018 (**Federal Register**/Vol. 83, No. 127/Monday, July 2, 2018/Notices 30941).

In addition, all Indian Tribes that meet the definition of such Tribes in the Indian Health Care Improvement Act of 1976, 25 U.S.C. 1603(d), are automatically designated as population groups with primary medical care and dental health professional shortages. Further, the Health Care Safety Net Amendments of 2002 provides eligibility for automatic facility HPSA designations for all federally qualified health centers (FQHCs) and rural health clinics that offer services regardless of ability to pay. Specifically, these entities include FQHCs funded under section 330 of the PHS Act, FQHC Look-Alikes, and Tribal and urban Indian clinics operating under the Indian Self-Determination and Education Act of 1975 (25 U.S.C. 450) or the Indian Health Care Improvement Act. All of these entities identified by May 1, 2019 are included on this listing. Absence from this list does not exclude them from HPSA designation; facilities eligible for automatic designation are included in the database when they are identified.

Each list of designated HPSAs is arranged by state. Within each state, the list is presented by county. If only a portion (or portions) of a county is (are) designated, a county is part of a larger designated service area, or a population group residing in a county or a facility located in the county has been designated, the name of the service area, population group, or facility involved is