• *Energy-related activities*—Projects that promote traditional energy activities and practices that support conservation and help to mitigate the high costs of the purchase, transportation, and storage of fuel in Alaskan Villages, especially strategic energy plans that have been identified in tribally approved strategic energy plans. Examples include projects to implement renewable energy resources at the Village level such as bio-energy, geothermal, hydropower, solar, wind, or other methods appropriate to the geographical location.

• *Infrastructure*—Developing Village-level infrastructure (transportation systems, communication, distribution networks, financial institutions, etc.) to support the Village workforce and to make sustainable business activity possible.

• *Subsistence*—Enhancing subsistence and agricultural activities to retain or revitalize traditional food sources and practices at the Village-level.

(c) *Social Development:* Projects that develop and implement culturally appropriate strategies to meet the social service needs of Alaska Natives. Examples of Alaska-Specific program areas of interest are:

• *Community living*—Development and coordination of services to assist people with disabilities by helping them reach their maximum potential through increased independence, productivity, and integration within the Village community.

• *Early childhood education and development*—Supporting stable and high-quality, culturally responsive early childhood programs, creating early childhood education and development jobs, and improving Village level planning and coordination of early childhood education and development programs.

• *Youth development*—Improving the well-being of youth through life skills training at the Village level, workforce development, mentoring programs, substance abuse programs, and preventing suicides and juvenile crime.

• *Community Health*—Promoting improved access to health care and quality of care through coordinated Village and regional approaches, expanding access to healthy foods available in Native Villages, and supporting environmental health.

• *Arts and culture*—Developing or enhancing activities, at the Village level that promote, preserve, or restore Native Village culture and arts.

• *Rescue archaeology*—Recovery of cultural material due to climate change such as exposure of cultural artifacts due to permafrost melting.

• *Organizational Development*—Increasing organizational capacity at the Village level to successfully implement mission and goals.

• *Nutrition and Fitness*—Promoting increased knowledge and participation in activities that promote healthy foods, active lifestyles, the reduction of obesity, and other healthy-living habits

• *Strengthening Families*—Incorporating culturally relevant strategies to strengthen families and promote family preservation, responsible parenting, and healthy relationship skills; and to foster the well-being of children residing in Villages

• *Responsible Fatherhood*—Supporting responsible fatherhood through activities such as counseling, mentoring, marriage education, enhancing relationship skills, parenting, and activities to foster economic stability

• *Suicide Prevention*—Promoting safety, resilience, and protective factors necessary to foster mental health and reduce incidences of suicide and suicidal ideation

• *Human Trafficking*—Development of Village-level assessments and strategies to address human trafficking, including efforts to bring awareness of human trafficking to the public, development of prevention strategies to address the needs of victims, and establishment of collaborative partnerships including those that train public safety officials to recognize traffickers and their victims.

C. Eligible Applicants

Applicants eligible under the Alaska-Specific SEDS FOA are those listed in 45 CFR 1336.33(a)(2): that is, ''(i) Federally recognized Indian tribes in Alaska; (ii) Alaska Native villages as defined in the Alaska Native Claims Settlement Act (ANSCA) and/or non-profit village consortia; (iii) Incorporated nonprofit Alaska Native multi-purpose community-based organizations; (iv) Nonprofit Alaska Native Regional Corporations/Associations in Alaska with village specific projects; and (v) Nonprofit Native organizations in Alaska with village specific projects.'' As this listing already appears in our regulations we are not seeking comment on this aspect of the Alaska-Specific SEDS Projects.

Statutory Authority: This notice for public comment is required by Section 814 of the Native American Programs Act of 1974 (NAPA), as amended.

Kimberly Romine,

Deputy Commissioner, Administration for Native American.

[FR Doc. 2014–26426 Filed 11–5–14; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0509]

Agency Information Collection Activities; Proposed Collection; Comment Request; Appeals of Science-Based Decisions Above the Division Level at the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 information collection requirements for appeals of science-based decisions above the division level at the Center for Veterinary Medicine (CVM).

DATES: Submit electronic or written comments on the collection of information by January 5, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Appeals of Science-Based Decisions Above the Division Level at CVM—21 CFR Part 10.75 (OMB Control Number 0910–0566)—Revision

Respondents: Respondents to this collection of information are applicants that wish to submit a request for review of a scientific dispute.

CVM's Guidance for Industry #79—''Dispute Resolution Procedures for Science-based Decisions on Products Regulated by the Center for Veterinary Medicine,'' describes the process by which CVM formally resolves disputes relating to scientific controversies. A scientific controversy involves issues concerning a specific product regulated by CVM related to matters of technical expertise and requires specialized education, training, or experience to be understood and resolved. Further, the guidance details information on how the Agency intends to interpret and apply provisions of the existing regulations regarding internal Agency review of decisions. In addition, the guidance outlines the established procedures for persons who are sponsors, applicants or manufacturers, for animal drugs or other products regulated by CVM, that wish to submit a request for review of a scientific dispute. When a sponsor, applicant, or manufacturer has a scientific disagreement with a written decision by CVM, they may submit a request for a review of that decision by following the established Agency channels of supervision for review.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
10.75	2	4	8	10	80

CVM encourages applicants to begin the resolution of science-based disputes with discussions with the review team/group, including the Team Leader or Division Director. The Center prefers that differences of opinion regarding science or science-based policy be resolved between the review team/group and the applicant. If the matter is not resolved by this preferred method, then CVM recommends that the applicant follow the procedure in Guidance for Industry #79. Of the two respondents who were advised on the procedure during the past 3 years, one has not followed up to initiate it and the other is working with the review team/group to resolve the issue(s). Therefore, this estimated annual reporting burden is based on CVM's previous experience in handling formal appeals for scientific disputes.

Dated: October 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26307 Filed 11–5–14; 8:45 am]

BILLING CODE 4164–01–P

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0984]

Specification of the Unique Facility Identifier System for Drug Establishment Registration; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Specification of the Unique Facility Identifier (UFI) System for Drug Establishment Registration.'' This guidance specifies the UFI system for registration of domestic and foreign drug establishments. The guidance addresses provisions set forth in the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). This guidance finalizes the draft guidance issued on September 6, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the