DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3019]

Transit Times to Slaughter Facilities, Milking Frequency, and Interpretation of Zero-Day Withdrawal Periods and Zero-Day Milk Discard Times Assigned to New Animal Drugs; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is soliciting comments on transit times to slaughter, milking frequency, and how end users interpret zero-day withdrawal period or zero-day milk discard time statements found on new animal drug labeling.

DATES: Submit either electronic or written comments by October 8, 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 October 8, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 8, 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–3019 for ''Transit Times to Slaughter Facilities, Milking Frequency, and Interpretation of Zero-Day Withdrawal Periods and Zero-Day Milk Discard Times Assigned to New Animal Drugs.'' 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: Charli M. Long-Medrano, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Place, Rm. E340, Rockville, MD 20855, 240–402–0850, *Charli.Long-Medrano@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

New animal drugs are assigned withdrawal periods and milk discard times when approved for use in food-producing animals. The withdrawal period or milk discard time is the interval between the time of the last administration of a new animal drug and the time when the animal can be slaughtered safely for human food or the milk can be consumed safely by humans, respectively.[1] Zero-day withdrawal periods and zero-day milk discard times are assigned to new animal drugs when the labeling indications and directions (*i.e.,* the approved conditions of use) allow entry of edible tissues, including milk, into the human food supply without regard to the elapsed time following the last drug administration.[2] In most instances, we assign a zero-day withdrawal period or zero-day milk discard time to new animal drugs when data or information demonstrate that edible tissues or milk can be consumed safely at timepoints known as practical zero withdrawal or practical zero-milk discard time, respectively. Practical zero withdrawal [3] and practical zero-milk discard time are

[1] Guidance for Industry #3, ''General Principles for Evaluating the Human Food Safety of New Animal Drugs Used in Food-Producing Animals'' (*https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052180.pdf*).

[2] Guidance for Industry #207 (VICH GL48), ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to Establish Product Withdrawal Periods'' (*https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM207941.pdf*).

[3] Ibid.

the shortest time intervals, including transit time to a slaughter facility, between administration of the last dose of the drug and slaughter or collection of milk for human consumption, respectively.

Since the 1980s, the Agency has assumed that poultry spent at least 6 hours in transit to a slaughter facility, cattle and pigs spent at least 12 hours in transit to a slaughter facility, and dairy cows were milked at 12-hour intervals. These assumptions led the Agency to define practical zero withdrawal as 6 hours for poultry and 12 hours for cattle and pigs and practical zero-milk discard time as 12 hours for lactating dairy cows. Accordingly, we currently assign a zero-day withdrawal period or zero-day milk discard time to new animal drugs if data from scientific studies or other available information confirm that residue concentrations in edible tissues or milk from treated animals are safe for human consumption after 6 hours withdrawn from drug for poultry or after 12 hours withdrawn from drug for cattle, pigs, sheep, goats, and lactating dairy animals (*i.e.,* practical zero withdrawal and practical zero-milk discard time). A zero-day withdrawal period or zero-day milk discard time is often communicated to the end user by a labeling statement (*e.g.,* ''zero-day withdrawal period,'' ''zero-day milk discard time,'' or ''no withdrawal period or milk discard time is required'').

The concept of practical zero withdrawal does not apply to drugs administered to laying hens (eggs only), food-producing aquatic animals, or honey bees. In these situations, we apply an ''absolute zero withdrawal approach,'' meaning that collection time or transit time is not considered and drug residues in eggs from treated hens, edible tissues from treated food-producing aquatic animals, and honey from treated honey bees must be below the assigned tolerance at all times during and after administration of a drug that has been assigned a zero-day withdrawal. Samples intended to support a zero-day withdrawal in these species are collected while animals are on the drug or immediately following the final drug administration.

II. Issues for Consideration

We recognize that the animal agriculture industry has undergone significant changes since the 1980s, when the current assumptions about transit time to slaughter and milking frequency were formulated. An accurate understanding of current industry practices and the end user's interpretation of labeling statements is necessary to approve labeling that ensures the safe and effective use of new animal drugs, which is central to our mission to protect and promote public health. Therefore, we are requesting comments on current industry practices regarding transit times to slaughter for food-producing animals, milking frequency, and how end users interpret a zero-day withdrawal period or zero-day milk discard time. We welcome comments on these topics for all food-producing animals except laying hens, honey bees, and food-producing aquatic animals because, as noted earlier, the concept of practical zero withdrawal does not apply to these classes of food-producing animals.

We invite comments on any or all the questions from individuals with direct knowledge of current industry practices. Please include the sector within the industry from where this information is derived (*e.g.,* a veterinarian, cooperative, individual producer, hauler, trade organization, packers and processors, etc.), as well as the source of the information (*e.g.,* survey, farm practices, published information, etc.) We specifically request comment on the following:

1. What is the minimum amount of time that food-producing animals spend in transit to a slaughter facility in the United States (*i.e.,* minimum transit time)? Please include the animal species and animal class(es) for each time provided.

2. What is the minimum amount of time that food-producing animals spend at slaughter facilities in the United States prior to being slaughtered for human consumption (*i.e.,* minimum holding time)? Please include the animal species and animal class(es) for each time provided.

3. What milking frequencies do United States commercial dairy operations commonly use (*e.g.,* two times per day, three times per day, greater than three times per day)? To what extent is each milking frequency used nationally, regionally, or within a particular sector (*e.g.,* 25 percent of dairies nationally, 30 percent of dairies in the Midwest, 50 percent of dairies serviced by a veterinary practice, etc.)?

4. How do end users of new animal drugs interpret labeling that has a ''zero-day withdrawal period'' or ''zero-day milk discard time,'' or that states ''no withdrawal period or milk discard time is required''?

We will consider the submitted comments to evaluate if our current approach to assigning zero-day withdrawal periods and zero-day milk discard times to new animal drugs is appropriate.

Dated: August 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17053 Filed 8–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Tribal Self-Governance; Negotiation Cooperative Agreement

Announcement Type: New.

Funding Announcement Number: HHS–2019–IHS–TSGN–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.444.

Key Dates

Application Deadline Date: October 23, 2019.

Earliest Anticipated Start Date: November 22, 2019.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Tribal Self-Governance (OTSG) is accepting applications for Negotiation Cooperative Agreements for the Tribal Self-Governance Program (TSGP). This program is authorized under Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). This program is described in the Assistance Listings located at *https://beta.sam.gov* (formerly known as Catalog of Federal Domestic Assistance) under 93.444.

Background

The TSGP is more than an IHS program; it is an expression of the Government-to-Government relationship between the United States (U.S.) and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions, and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP affords Tribes the most flexibility to tailor health care PSFAs and is one of three ways that Tribes can choose to obtain health care from the Federal Government for their citizens. Specifically, Tribes can choose to: (1) Receive health care services directly from the IHS; (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-