and dental insurance plans that have been certified as meeting certain standards.

In the final rule, the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 (CMS–9937–F), we finalized 45 CFR 156.1256, which requires QHP issuers, in the case of a material plan or benefit display error included in 45 CFR 155.420(d)(12), to notify their enrollees of the error and the enrollees' eligibility for a special enrollment period (SEP) within 30 calendar days after the issuer is informed by an Federally-facilitated Exchange (FFE) that the error is corrected, if directed to do so by the FFE. This requirement provides notification to QHP enrollees of errors that may have impacted their QHP selection and enrollment and any associated monthly or annual costs, as well as the availability of an SEP under § 155.420(d)(12) for the enrollee to select a different QHP, if desired. The Centers for Medicare and Medicaid Services (CMS) is renewing this information collection request (ICR) in connection with standards regarding Plan or Display Errors SEPs. The title of the package has been changed to better reflect its subject matter. The burden estimate for the ICR included in this package reflects the time and effort for QHP issuers to provide notifications to enrollees on the ICRs regarding Plan or Display Errors SEPs. *Form Number:* CMS–10595 (OMB control number: 0938–1301); *Frequency:* Yearly; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions); *Number of Respondents:* 505; *Total Annual Responses:* 3,400; *Total Annual Hours:* 1,700. (For questions regarding this collection contact Deborah Hunter at 202–309–1098).

Dated: September 20, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–20856 Filed 9–24–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3614]

Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue To Be Available Over-the-Counter; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a draft guidance for industry (GFI) #263 entitled ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.'' This draft guidance document, when finalized, will provide information to sponsors of medically important antimicrobial new animal drug products who are interested in changing the approved marketing status of these products from over-the-counter (OTC) to by veterinary prescription (Rx) consistent with FDA's recommendation that the use of such drugs in animals be limited to uses that include veterinary oversight to mitigate development of antimicrobial resistance. It also will recommend timeframes for stakeholders wishing to comply voluntarily with this guidance.

DATES: Submit either electronic or written comments on the draft guidance by December 24, 2019 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–2019–D–3614 for ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.'' 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 guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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 document.

FOR FURTHER INFORMATION CONTACT: Cindy Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0817, email: *cindy.burnsteel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #263 entitled ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.'' This draft guidance, when finalized, will provide information to sponsors of certain new animal drug products who are interested in changing the approved marketing status of these products from OTC to Rx consistent with FDA's recommendation that the use of such drugs in animals be limited to uses that include veterinary oversight in order to mitigate development of antimicrobial resistance and thereby preserve the effectiveness of these drugs for use as therapies to treat infections in humans and animals. The draft guidance, when finalized, also will recommend timeframes for stakeholders wishing to comply voluntarily with this guidance.

In 2016, in response to recommendations made by FDA as part of a strategy to address antimicrobial resistance associated with the use of antimicrobial drugs in animal agriculture, sponsors of all medically important antimicrobial drugs approved for use in or on the feed or drinking water of food-producing animals worked with FDA to voluntarily withdraw approval of indications that were not considered necessary for assuring animal health (production indications), and voluntarily change all remaining approved uses of such new animal drugs from OTC to either Veterinary Feed Directive or Rx marketing status, as applicable.[1]

Although all medically important antimicrobials used in feed or water for food-producing animals are currently under veterinary oversight, some other dosage form products (*e.g.,* injectable, tablet, intramammary infusion) intended for use in food-producing and non-food-producing animals remain available OTC. This draft guidance, when finalized, will provide sponsors with specific recommendations on how to facilitate voluntary changes to the approved conditions of use of these drugs to prescription marketing status. The voluntary process outlined in this draft guidance will help to ensure new animal drugs containing antimicrobials of human medical importance are administered only under veterinary oversight and only for therapeutic uses.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on veterinary oversight of medically important antimicrobial drugs administered to animals. It does not establish any rights for any person and is 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 draft guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance 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 section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov*.

Dated: September 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20688 Filed 9–23–19; 11:15 am]

BILLING CODE 4164–01–P

[1] See GFI #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed*)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Assistant Secretary for Administration; Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Secretary for Preparedness and Response (ASPR); the Director, Centers for Disease Control and Prevention (CDC); the Administrator, Health Resources and Services Administration (HRSA); the Director, National Institutes for Health (NIH); the Director, Office of Global Affairs (OGA); and the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA) the authority vested in the Secretary by section 212(l) of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (FY 19 HHS Appropriations Act) Public Law 115–245, division B, title II, (September 28, 2018), or substantially similar authorities vested in me in the future by Congress, in order to carry out international health activities, including HIV/AIDS and other infectious disease, chronic and environmental disease, and other health activities abroad. Section 212(l) of the FY19 HHS Appropriations