the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Steven Fleischer, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0809, *Steven.Fleischer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #276 entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs.'' The recommended approach to demonstrate substantial evidence of effectiveness of an investigational new animal drug intended for the prevention of heartworm disease in dogs is for the sponsor to conduct two laboratory dose confirmation studies and one multisite field effectiveness study in accordance with the principles of good clinical practice as described in GFI #85 (VICH GL9), ''Good Clinical Practice.'' This draft guidance provides detail regarding FDA's recommendations for the effectiveness evaluation of drugs indicated for the prevention of heartworm disease caused by *Dirofilaria immitis* in dogs. This guidance is informed by comments FDA received in response to the ''Evaluation of Approaches To Demonstrate Effectiveness of Heartworm Preventatives for Dogs; Request for Comments,'' which published in the **Federal Register** on May 24, 2018 (83 FR 24122).

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Effectiveness of Anthelmintics: Specific Recommendations for Products Proposed for the Prevention of Heartworm Disease in Dogs.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: November 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26059 Filed 11–29–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2855]

Mylan Institutional, Inc.; Withdrawal of Approval of a New Drug Application for SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of new drug application (NDA) 019832 for SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution, held by Mylan Institutional, Inc., a Viatris company (Mylan). Mylan has voluntarily requested withdrawal of this application and has waived its opportunity for a hearing.

DATES: Applicable November 30, 2022.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301–796–3601.

SUPPLEMENTARY INFORMATION: On June 5, 1998, the Food and Drug Administration (FDA) approved NDA 019832 for SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution, under the Agency's accelerated approval regulations (see generally 21 CFR subpart H). It was approved for ''for use as an adjunctive topical antimicrobial agent to control bacterial infection when used under moist dressings over meshed autografts on excised burn wounds.''

NDA 019832's accelerated approval was ''subject to the requirement that the applicant study the drug further, to verify and describe its clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome'' (21 CFR 314.510). To date, however, Mylan has not completed the required confirmatory study. Mylan acknowledged in its December 10, 2021, letter requesting withdrawal of approval that a successful confirmatory study was necessary to fulfill the accelerated approval requirements, but stated that conducting such a study is not feasible. Mylan thus requested that NDA 019832 be withdrawn under 21 CFR 314.150(d), and waived its right to a hearing.

Thus, for the reasons discussed above, under 21 CFR 314.150(d), approval of NDA 019832 for SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution, and all amendments and supplements thereto, is withdrawn. Distribution of SULFAMYLON® (Mafenide Acetate, USP) Powder for 5% Topical Solution in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: November 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–26057 Filed 11–29–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0099]

Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request; and Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Final Guidance for Industry

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