Understanding of Epidemiology of Coccidioidomycosis in the Western Hemisphere,'' *Annals of the New York Academy of Sciences,* epub ahead of print March 29, 2007, doi: 10.1196/annals.1406.004.
31. Wack, E.E., N.M. Ampel, R.H. Sunenshine, and J.N. Galgiani, 2015, ''The Return of Delayed-Type Hypersensitivity Skin Testing for Coccidioidomycosis,'' *Clinical Infectious Diseaes,* epub ahead of print May 15, 2015, doi: 10.1093/cid/civ388.
32. Laniado-Laborin, R., E.G. Arathoon, C. Canteros, et al., ''Coccidioidomycosis in Latin America,'' *Medical Mycology,* 57(1 Suppl):S46–S55.
33. Giacomazzi, J., L. Baethgen, L.C. Carneiro, et al., in association with the LIFE Program, 2016, ''The Burden of Serious Human Fungal Infections in Brazil,'' *Mycoses,* epub ahead of print December 22, 2015, doi: 10.1111/myc.12427.
34. González-Benavides, J., 1991, ''The Panorama of Coccidioidomycosis in Nuevo Leon from 1978 to 1988,'' *Gaceta Medica de Mexico,* 127(5):427–432.
35. Sondermeyer Cooksey, G., L.A. Lee, D. Gilliss, et al., 2013, ''Coccidioidomycosis-Associated Hospitalizations, California, USA, 2000–2011,'' *Emerging Infectious Diseases,* 10:1590–1597.
36. Sondermeyer Cooksey, G., L.A. Lee, D. Gilliss, and D.J. Vugia, 2016, ''Coccidioidomycosis-Associated Deaths in California, 2000–2013,'' *Public Health Reports,* 131(4):531–535.
37. Ampel, N.M. 2005, ''Coccidioidomycosis in Persons Infected With HIV Type 1,'' *Clinical Infectious Diseases,* epub ahead of print September 12, 2005, doi: 10.1086/444502.
38. Benedict, K., O.Z. McCotter, S. Brady, et al., 2019, ''Surveillance for Coccidioidomycosis—United States, 2011–2017,'' *MMWR Surveillance Summaries,* 68(7):1–15.
39. Lee, L.A., G. Sondermeyer Cooksey, J.J. Kim, et al., 2019, ''Pediatric Coccidioidomycosis: Case Series From a California Pediatric Infectious Diseases Clinic,'' *Pediatric Infectious Disease Journal,* 38(2):115–121.
40. Sondermeyer Cooksey, G., L.A. Lee, D. Gilliss, et al., ''Epidemiology of Pediatric Coccidioidomycosis in California, 2000–2012,'' *Pediatric Infectious Disease Journal,* 35(2):166–171.
41. Wheeler, C., K.D. Lucas, and J.C. Mohle-Boetani, 2015, ''Rates and Risk Factors for Coccidioidomycosis Among Prison Inmates, California, USA, 2011,'' *Emerging Infectious Diseases,* 21(1):70–75.
42. U.S. District Court for the Northern District of California, 2013, *Plata* v. *Brown,* No. C01–1351 TEH, s.l.
43. Benedict, K., M. Ireland, M.P. Weinberg, et al., 2018, ''Enhanced Surveillance for Coccidioidomycosis, 14 U.S. States,'' *Emerging Infectious Diseases,* 242(8)1444–1452.
44. Garrett, A.L., Y.H. Chang, K. Ganley, and J.E. Blair, 2016, ''Uphill Both Ways: Fatigue and Quality of Life in Valley Fever,'' *Medical Mycology,* epub ahead of print November 26, 2015, doi: 10.1093/mmy/myv097.

Dated: July 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15255 Filed 7–14–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1997–D–0444]

Special Considerations, Incentives, and Programs To Support the Approval of New Animal Drugs for Minor Uses and for Minor Species; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of draft guidance for industry (GFI) #61 entitled ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' This draft guidance is intended to assist those interested in pursuing FDA approval of new animal drugs intended for minor uses in major species or for use in minor species (MUMS drugs). It outlines the basic statutory and regulatory requirements and special considerations for these approvals, and describes the incentives available to encourage the development of MUMS drugs.

DATES: Submit either electronic or written comments on the draft guidance by November 12, 2020 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–1997–D–0444 for ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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: Margaret Oeller, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0566, *margaret.oeller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of draft GFI #61 entitled ''Special Considerations, Incentives, and Programs to Support the Approval of New Animal Drugs for Minor Uses and for Minor Species.'' This draft guidance replaces final GFI #61, issued in April 1999 (with a minor update in May 2008) entitled ''FDA Approval of New Animal Drugs for Minor Uses and for Minor Species.'' This draft guidance, when finalized, should assist those interested in pursuing FDA approval of MUMS drugs. It outlines the basic statutory and regulatory requirements and special considerations for these approvals, and describes the incentives available to encourage the development of MUMS drugs.

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 approval MUMS drugs. 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

FDA tentatively concludes that this draft guidance contains no collection 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.

However, this draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 511 have been approved under OMB control number 0910–0117; in 21 CFR part 514 have been approved under OMB control numbers 0910–0032 and 0910–0284; and in 21 CFR part 516 have been approved under OMB control numbers 0910–0605 and 0910–0620.

III. 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: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15203 Filed 7–14–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1980–N–0038 (formerly 80N–0012)]

Vioform-Hydrocortisone Cream, Ointment, and Lotion Containing Iodochlorhydroxyquin and Hydrocortisone; Final Decision on Proposal To Withdraw Approval of New Drug Applications; Opportunity To Affirm Outstanding Appeal

AGENCY: Food and Drug Administration; HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing that the Initial Decision of the Administrative Law Judge (ALJ), to withdraw approval of the new drug application (NDA) for Vioform-Hydrocortisone Cream, Ointment, and Lotion containing Iodochlorhydroxyquin and Hydrocortisone (Vioform), is the final decision of the Commissioner by operation of law. Several parties to the hearing, including the NDA holder and identical, related, or similar (IRS) product manufacturers, and a non-party participant timely filed exceptions to the ALJ's Initial Decision. FDA recently requested that the current owner of the NDA application, the IRS product manufacturers, and the non-party participant that had timely filed exceptions, or their successors-in-interest, affirm within a specific timeframe their interest in pursuing their appeals of the ALJ's Initial Decision. The NDA holder responded within the timeframe and withdrew its appeal. No other appellants that received actual notice of the Agency's request responded within the timeframe. Accordingly, FDA now deems any exceptions filed by appellants that received notice of the Agency's request to be withdrawn. FDA is, however, offering an opportunity to other IRS product manufacturers, or successors-in-interest, that submitted exceptions to the ALJ's Initial Decision and did not receive notice of FDA's request, to affirm their desire to pursue the appeal. The ALJ's Initial Decision is the final decision of the Commissioner by operation of law; however, if FDA receives a valid request to affirm the appeal, as described in this notice, we will withdraw this notice.

DATES: This notice is applicable July 15, 2020. Any affirmation of interest in pursuing an appeal should be submitted to the docket by August 14, 2020.

ADDRESSES: For access to the docket, 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 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION: