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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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 This draft guidance replaces final GFI #61, issued in April 1999 (with a minor update in May 2008) entitled ''FDA Approval of New Animal Drugs for Minor Uses and for Minor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 This draft guidance, when finalized, should assist those interested in pursuing FDA approval of MUMS drugs.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This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on approval MUMS drugs.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]

BILLING CODE 4164–01–P

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:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act) was amended by the Drug Amendments Act of 1962, and these amendments provided that new drugs could no longer be approved unless both safety and efficacy had been established for them. As amended, the FD&C Act also required FDA to evaluate drugs approved as safe between 1938 and 1962 to determine whether such drugs were effective and to withdraw approval for any NDA where there was not substantial evidence of the drug's effectiveness. The person contesting the withdrawal of the approval had the burden of coming forward with evidence of effectiveness for the drug. FDA's review of these pre-1962 drugs is known as the Drug Efficacy Study Implementation program.

In a document published in the **Federal Register** of June 20, 1972 (37 FR 12171, available at *https://www.govinfo.gov/content/pkg/FR-1972-06-20/pdf/FR-1972-06-20.pdf*), after receiving reports from the National Academy of Sciences/National Research Council, Drug Efficacy Study Group, and other available evidence, FDA classified Vioform as ''possibly effective'' for its labeled indications relating to use in various dermatoses or as anti-infective agents. Thereafter, Ciba Pharmaceutical Co., the NDA holder of Vioform (NDA 10–412) submitted data intended to support the effectiveness of Vioform. In a document published in the **Federal Register** of September 25, 1981 (46 FR 47408, available at *https://www.govinfo.gov/content/pkg/FR-1981-09-25/pdf/FR-1981-09-25.pdf*), the Director of the Bureau of Drugs (now the Center for Drug Evaluation and Research), after reviewing all the data previously submitted, concluded that Vioform lacks substantial evidence of effectiveness for its labeled indications and that the submitted data do not demonstrate that each component of Vioform makes a significant contribution to the claimed effects of the drug. Further, the Director issued a notice of opportunity for hearing on a proposal to withdraw approval of Vioform.

Ciba-Geigy Corporation (Ciba-Geigy) (formerly Ciba Pharmaceutical Co.) and multiple IRS product manufacturers responded to the notice of opportunity for hearing and submitted requests for hearing. By notice published in the **Federal Register** of August 21, 1984 (49 FR 33173, available at *https://www.govinfo.gov/content/pkg/FR-1984-08-21/pdf/FR-1984-08-21.pdf*), the Commissioner granted a hearing. Following the submission of written testimony and documentary evidence, an ALJ, Daniel J. Davidson, conducted a hearing, which concluded on December 4, 1985. He issued his Initial Decision on February 5, 1988. The ALJ found: (1) That the effectiveness of Vioform had not been established by substantial evidence of adequate and well-controlled studies, (2) that the requirements of the combination drug policy had not been met, and (3) that Vioform is a new drug under 21 U.S.C. 321(p). Ciba-Geigy, the IRS product manufacturers, and one non-party participant timely appealed the ALJ's Initial Decision by filing exceptions with the Commissioner under § 12.125 (21 CFR 12.125).

FDA recently sent letters to persons that submitted timely exceptions or that FDA identified as successors-in-interest to parties that submitted timely exceptions. The letters requested that the persons that filed exceptions to the ALJ's Initial Decision, or their successors-in-interest, affirm their intent to pursue their appeals and informed them that, if they did not respond and affirm their desire to pursue their appeal by a specified date, the Office of the Commissioner would conclude that they no longer wish to pursue the appeal of the ALJ's Initial Decision and would proceed as if the appeal has been withdrawn. The Office of the Commissioner received a response from Novartis, the current NDA holder and successor-in-interest to Ciba-Geigy. In its letter, Novartis states that it does not wish to pursue the appeal of the ALJ's Initial Decision. The letter also references a previous request to withdraw the approval of the NDA for Vioform and states that Novartis expects ''the NDA withdrawal in due course.''

The Office of the Commissioner also received a letter from Mr. Edward John Allera (Mr. Allera) on behalf of an unidentified client on October 23, 2017. In that letter, Mr. Allera stated that he represented a client that was in the process of acquiring an interest in an IRS product for which the original manufacturer filed timely exceptions. Mr. Allera stated that he would like to affirm his client's intent to pursue the other manufacturer's appeal of the ALJ's Initial Decision. By letter dated December 21, 2017, Mr. Allera reaffirmed his client's wish to pursue the appeal after acquiring an interest in the IRS product. Mr. Allera's October 2017 letter made clear that, as of the date specified to respond, his client neither had appealed the ALJ's Initial Decision in this proceeding by timely filing exceptions nor was, at that time, a successor-in-interest to a party that filed exceptions. Only parties that submitted timely exceptions or were actual successors-in-interest to parties that submitted timely exceptions could affirm an interest in pursuing the appeal. See § 12.125(a). Given that Mr. Allera's client met neither criterion, Mr. Allera's client had no existing qualifying interest in pursuing the appeal to affirm.

The Office of the Commissioner did not receive a response from any IRS product manufacturers, or their successors-in-interest, that filed timely exceptions to the ALJ's Initial Decision and that received notice of the Agency's request to affirm their interest in pursuing their appeals of the ALJ's Initial Decision. The deadlines for responding to the Agency's requests have now passed. Therefore, the Commissioner now deems the exceptions filed by appellants that received notice of the Agency's requests to be withdrawn.

Despite FDA's efforts, based upon the responses to the recent letters, FDA cannot eliminate the possibility that there might be parties or successors-in-interest that filed timely exceptions but did not receive FDA's letter. FDA is thus providing an opportunity for any such person to affirm its interest in pursuing its appeal. The Agency will only deem effective affirmations from persons that did not receive a letter from FDA and that can establish: (1) That the person is a party or a successor-in-interest to a party that submitted timely exceptions and (2) that the person was a party or a successor-in-interest during the time designated for it to respond to FDA's recent letters. Any affirmation of interest in pursuing an appeal should be submitted to the docket by (see **DATES**). The submission should include documentation verifying that the person is a party or successor-in-interest to a party that submitted timely exceptions and a statement that the person wishes to pursue the appeal of the ALJ's Initial Decision. FDA will withdraw this notice if we receive a timely affirmation of interest and confirm that the person meets the requisite criteria.

II. Conclusion and Order

Given that the exceptions have all been withdrawn or deemed withdrawn, this proceeding is now in the same procedural posture as if no exceptions had ever been filed. When parties do not file exceptions to the ALJ's Initial Decision, and the Commissioner does not file a notice of review, the ALJ's Initial Decision becomes the final decision of the Commissioner (see § 12.120(e) (21 CFR 12.120(e))). FDA will publish a notice in the **Federal Register** when an initial decision

becomes the final decision of the Commissioner without appeal to or review by the Commissioner (see § 12.120(f)). Therefore, the ALJ's Initial Decision is the final decision of the Commissioner effective 90 days after publication of this notice.

Pursuant to the findings in the ALJ's Initial Decision, under section 505(e) of the FD&C Act (21 U.S.C. 355(e)), there is a lack of substantial evidence that Vioform will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling for the treatment of primary fungal infections or secondarily infected dermatoses. Further, Vioform does not meet the combination drug policy in 21 CFR 300.50 and is a ''new drug'' within the meaning of 21 U.S.C. 321(p). Therefore, approval of the NDA for Vioform is withdrawn October 13, 2020. Distribution of products subject to the Initial Decision in interstate commerce without an approved application is prohibited and subject to regulatory action (see, *e.g.,* sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

The full text of the ALJ's Initial Decision may be seen at Dockets Management Staff (Ref. 1).

III. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.*

1. Initial Decision, Docket No. 80N–0012, ''Proposal to Withdraw Approval of the New Drug Application for Vioform-Hydrocortisone Cream, Ointment and Lotion Containing Iodochlorhydroxyquin and Hydrocortisone under the Drug Efficacy Study Implementation Program.''

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15298 Filed 7–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1402]

Biomarkers and Surrogate Endpoints in Clinical Studies To Support Effectiveness of New Animal Drugs; 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 a draft guidance for industry (GFI) #267 entitled ''Biomarkers and Surrogate Endpoints in Clinical Studies Support Effectiveness of New Animal Drugs.'' The draft guidance, if finalized, will describe FDA's current thinking with respect to assisting sponsors in incorporating biomarkers and surrogate endpoints into proposed clinical investigation protocols and applications for new animal drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by October 13, 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–2020–D–1402 for ''Biomarkers and Surrogate Endpoints in Clinical Studies to Support Effectiveness of New Animal Drugs.'' 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.*