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)(3)). Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HPV–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 See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.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 (HPV–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 This draft guidance replaces final GFI #61, issued in April 1999 (with a minor update in May 2008) entitled “FDA Approval of New Animal Drugs for Minor Uses and for Minor Species.” This draft guidance, when finalized, will represent the current thinking of FDA on approval MUMS drugs.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FDA tentatively concludes that this draft guidance contains no collection of information.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 0910–0032 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.

Lowell J. Schiller, Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Viocform–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 Viocform–Hydrocortisone Cream, Ointment, and Lotion containing Iodochlorhydroxyquin and Hydrocortisone (Viocform), 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.


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, 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 Vioform and that received notice of the Agency’s request to affirm an interest in pursuing the appeal to affirm.

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 § 12.125(a) (21 CFR 12.125)). FDA will publish a notice in the Federal Register when an initial decision
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, 5600 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 http://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.


Lowell J. Schiller,
Principal Associate Commissioner for Policy.
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