necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to FRTIB officers and employees.

6. Routine Use—Third-Party Service Providers: A record from this system of records may be disclosed to third-party service providers, including other government agencies, such as the Department of Justice, that provide support for FRTIB's Insider Threat Program under a contract or interagency agreement.

7. Routine Use—Disclosure to Law Enforcement: Where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or charged with enforcing or implementing such law.

8. Routine Use—Litigation, DOJ or Outside Counsel: A record from this system of records may be disclosed to the Department of Justice, FRTIB's outside counsel, other Federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when: (1) FRTIB, or (2) any employee of FRTIB in his or her official capacity, or (3) any employee of FRTIB in his or her individual capacity where DOJ or FRTIB has agreed to represent the employee, or (4) the United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and FRTIB determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which FRTIB collected the records.

9. Routine Use—Litigation, Opposing Counsel: A record from this system of records may be disclosed to a court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena.

10. Routine Use—NARA/Records Management: A record from this system of records may be disclosed to the National Archives and Records Administration (NARA) or other Federal Government agencies pursuant to the Federal Records Act.

11. Routine Use—Insider Threat Community of Practice: A record from this system of records may be disclosed to any Federal agency or group of agencies with responsibilities for activities related to counterintelligence or the detection of insider threats.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in paper and electronic form, including on computer databases and cloud-based services, all of which are securely stored.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name, phone number, case number, or internal FRTIB identification (including FRTIB email, username, etc.).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records are maintained in accordance with General Records Schedule 5.6 (Security Records), Items 210 through 240, issued by the National Archives and Records Administration (NARA).

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

FRTIB has adopted appropriate administrative, technical, and physical controls in accordance with FRTIB's security program to protect the security, confidentiality, availability, and integrity of the information and to ensure that records are not disclosed to or accessed by unauthorized individuals. Access to the records in this system is limited to individuals who have the appropriate permissions and who have a need to know the information in order to perform their official duties.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records within this system must submit a request pursuant to 5 CFR part 1630. Attorneys or other persons acting on behalf of an individual must provide written authorization from that individual, such as a Power of Attorney, in order for the representative to act on their behalf.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

See Record Access Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Records in this system will be exempt, based on 5 U.S.C. 552a(k)(2), from the requirements in subsections (c)(3), (d)(1)–(4), (e)(1), (e)(4)(G)–(I), and (f) of the Privacy Act. The Agency has promulgated regulations implementing the Privacy Act at 5 CFR 1632.15 that establish this exemption.

HISTORY:

None.

[FR Doc. 2021–16016 Filed 7–27–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0299]

Determination That EFUDEX (Fluorouracil) Topical Solution, 5 Percent, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that EFUDEX (fluorouracil) topical solution, 5 percent, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of the abbreviated new drug application (ANDA) that refers to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6272, Silver Spring, MD 20993–0002, 240–825–9944, *Kaetochi.Okemgbo@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

EFUDEX (fluorouracil) topical solution, 5 percent, is the subject of NDA 016831, held by Bausch Health Americas, Inc., and initially approved on July 29, 1970. EFUDEX is indicated for the topical treatment of multiple actinic or solar keratoses, and treatment of superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesions or difficult treatment sites. EFUDEX (fluorouracil) topical solution, 5 percent, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Encube Ethicals Private Ltd. submitted a citizen petition dated March 16, 2021 (Docket No. FDA–2021–P–0299), under 21 CFR 10.30, requesting that the Agency determine whether EFUDEX (fluorouracil) topical solution, 5 percent, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that EFUDEX (fluorouracil) topical solution, 5 percent, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that EFUDEX (fluorouracil) topical solution, 5 percent, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of EFUDEX (fluorouracil) topical solution, 5 percent, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list EFUDEX (fluorouracil) topical solution, 5 percent, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of the approved ANDA that refers to this drug product. Additional ANDAs that refer to EFUDEX (fluorouracil) topical solution, 5 percent, may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16037 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0708]

Biosimilar User Fee Rates for Fiscal Year 2022

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2022. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2017 (BsUFA II), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application. BsUFA II directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year. These fees apply to the period from October 1, 2021, through September 30, 2022.

FOR FURTHER INFORMATION CONTACT: Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j-51, 379j-52, and 379j-53), as amended by BsUFA II (title IV of the FDA Reauthorization Act of 2017, Pub. L. 115–52), authorize the collection of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing or the sponsor discontinues participation in FDA's BPD program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program and wants to reengage with FDA on development of the product, the sponsor must pay a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA II also authorizes fees for certain biosimilar biological product