Records may be disclosed for a research, evaluation, or data purpose if HHS:

(A) Determines that the use and disclosure does not violate the laws or policies under which the record was collected;

(B) Determines that the purpose cannot be reasonably accomplished unless individually identifiable information is provided;

(C) Determines that the purpose warrants any privacy risk to the individual caused by the disclosure;

(D) Determines that the disclosure will not directly affect the rights, privileges, or benefits of a particular individual.

(E) Requires the recipient to:

1. Establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record;

2. Destroy the individually identifiable information as soon as reasonable for that project;

3. Not reuse or redisclose the information except:

(a) in an emergency circumstances affecting the health or safety of an individual,

(b) to another research, evaluation, or data project with written authorization from HHS,

(c) for an audit related to the project, if the individually identifiable information is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or

(d) when required by law; and

4. Provide HHS a written statement that they understand and will abide by these requirements.

(10) Disclosure to Continue Services

Records about the services an individual received from a grantee as part of an OPRE Project may be shared with that grantee, or successor organizations, to continue serving that individual.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are stored in paper and electronic form.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the subject individual's name, SSN, or another personal identifier contained in the records.

POLICIES AND PROCEDURES FOR RETENTION AND DISPOSAL OF RECORDS:

A disposition schedule, DAA–0292–2020–0005, is pending approval by NARA, which proposes at Item 1.3 that the records (background materials for creation of studies and reports) be cut off at the end of the calendar year in which the report is published and destroyed 5 years after cut-off. ACF/OPRE will continue to retain the records indefinitely until the schedule is approved by NARA.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All record keepers are required to maintain appropriate administrative, technical, and physical safeguards to protect the records from unauthorized access. Administrative controls include training individuals who have access to the records how to handle them appropriately, incident response plans, and limiting access to individuals who need to know the information. Technical controls include the use of antivirus software, vulnerability patching, multi-factor authentication when required, and storing electronic records in encrypted form. Physical controls include storing hard copy records and computer terminals used to access electronic records in physically locked locations when not in use.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about them in this system of records must submit a written access request to the System Manager identified in the ''System Manager(s)'' section of this SORN, in accordance with the Department's Privacy Act implementation regulations in 45 CFR. The request must contain the requester's full name, contact information (*i.e.,* telephone number and/or email address, and current mailing address), and sufficient identifying particulars contained in the records to enable the System Manager to distinguish between records on subject individuals with the same name. In addition, to verify the requester's identity, the request must be signed by the requester, and the signature must be notarized or the request must include the requester's written certification that the requester is the person the requester claims to be and that he/she understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000.

CONTESTING RECORD PROCEDURES:

Individuals seeking to amend a record about them in this system of records must submit a written amendment request to the System Manager identified in the ''System Manager(s)'' section of this SORN, in accordance with the Department's Privacy Act implementation regulations in 45 CFR. An amendment request must include verification of the requester's identity in the same manner required for an access request and must reasonably identify the record and specify the information being contested, the corrective action sought, and the reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether this system of records contains records about them must submit a written notification request to the System Manager identified in the ''System Manager(s)'' section of this SORN, in accordance with the Department's Privacy Act implementation regulations in 45 CFR and verify their identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

80 FR 17893 (April 2, 2015), 83 FR 6591 (Feb. 14, 2018).

[FR Doc. 2022–20139 Filed 9–16–22; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–0068]

Determination That ENDEP (Amitriptyline Hydrochloride) Oral Concentrate, 40 Milligrams/Milliliter, 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 ENDEP (amitriptyline hydrochloride) oral concentrate, 40 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224,

Silver Spring, MD 20993–0002, 301–796–1546, *Kaetochi.Okemgbo@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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.

ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, is the subject of ANDA 085749, held by Hoffman-La Roche Inc., and initially approved on December 23, 1977. ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, is indicated for relief of symptoms of depression.

Hoffman-La Roche Inc. has never marketed ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL. ANDA 085749 is listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated January 11, 2022 (Docket No. FDA–2022–P–0068), under 21 CFR 10.30, requesting that the Agency determine whether ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, 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 ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, 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. ANDAs that refer to ENDEP (amitriptyline hydrochloride) oral concentrate, 40 mg/mL, may 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: September 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20195 Filed 9–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6395]

Request for Applications for New Members of the Clinical Trials Transformation Initiative/Food and Drug Administration Patient Engagement Collaborative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for applications.

SUMMARY: The Food and Drug Administration (FDA or Agency), in collaboration with the Clinical Trials Transformation Initiative (CTTI), is requesting applications from patient advocates interested in participating on the Patient Engagement Collaborative (PEC). The PEC is an ongoing, collaborative forum coordinated through the Office of Patient Affairs, Office of Clinical Policy and Programs (OCPP), Office of the Commissioner at FDA, and is hosted by CTTI. Through the PEC, the patient community and regulators are able to discuss an array of topics regarding increasing meaningful patient engagement with diverse populations in medical product development and regulatory discussions at FDA. The activities of the PEC may include, but are not limited to, providing diverse perspectives on topics such as systematic patient engagement, transparency, and communication; providing considerations for implementing new strategies to enhance patient engagement at FDA; and proposing new models of collaboration in which patient and patient advocate perspectives are incorporated into general medical product development and regulatory processes.

DATES: Applications can be submitted starting at 11:59 p.m. eastern time on September 19, 2022. This announcement is open to receive a maximum of 75 applications. Applications will be accepted until 11:59 p.m. eastern time on October 19, 2022 or until 75 applications are received, whichever happens first.

ADDRESSES: All applications should be submitted to FDA's Office of Patient Affairs in OCPP. The preferred application method is via the online submission system provided by CTTI, available at *https://duke.qualtrics.com/jfe/form/SV_5nI1VVWVOaD59ky.* For those applicants unable to submit an application electronically, please call FDA's Office of Patient Affairs at 301–796–8460 to arrange for mail or delivery