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 Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products; Draft Guidance for Industry.'' The draft guidance document is intended to assist sponsors, including industry and academic sponsors, developing CAR T cell products. The guidance includes CAR T cell-specific recommendations regarding CMC, pharmacology and toxicology, and clinical study design. While the guidance specifically focuses on CAR T cell products, much of the information and recommendations provided will also be applicable to other genetically modified lymphocyte products, such as CAR Natural Killer cells or T cell receptor-modified T cells.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another human gene therapy draft guidance document entitled ''Human Gene Therapy Products Incorporating Human Genome Editing: Draft Guidance for Industry.''

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance, when finalized, will represent the current thinking of FDA on ''Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections 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 for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 50 have been approved under OMB control number 0910–0755; the collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR part 1271 have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/* or *https://www.regulations.gov*.

Dated: March 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–05539 Filed 3–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1960]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: The Food and Drug Administration Safety Information and Adverse Event Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by April 15, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0291. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

OMB Control Number 0910–0291—Revision

I. Background

MedWatch is FDA's program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors associated with FDA-regulated

products. Examples of these products include prescription and over-the-counter medicines; biologics such as blood components, blood/plasma derivatives, and gene therapies; medical devices such as hearing aids, breast pumps, and pacemakers; combination products such as pre-filled drug syringe, metered-dose inhalers, and nasal spray; special nutritional products such as dietary supplements, medical foods, and infant formulas; cosmetics such as moisturizers, makeup, shampoos, hair dyes, and tattoos; and food, such as beverages and ingredients added to foods.

MedWatch receives reports from the public and, when appropriate, publishes safety alerts intended to protect the public health. More information regarding the MedWatch program, including user guides and consumer assistance on reporting problems to FDA, may be found on our website at *https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.* Reports are submitted to FDA by health professionals, patients, and consumers, and FDA issues an acknowledgement upon receipt of the report. Forms may be downloaded from our website at *https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting* and submitted by Fax or mail following the instructions; by completing and submitting forms online; or by calling FDA at 800–FDA–1088 (800–322–1088) and reporting by telephone.

Some adverse event reports (AERs) are required to be submitted to FDA (mandatory reporting), while other reporting is done voluntarily (voluntary reporting). Upon receipt of the report, it is directed to the FDA center responsible for ensuring the product's compliance with statutory requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and/or any related authorities. Certain requirements regarding mandatory reporting of adverse events or product problems have been codified in Agency regulations, including those found in 21 CFR parts 310, 314, 514, 600, 803, 1114, and 1271.

We are revising the information collection to include electronic submission of AERs, currently approved in OMB control number 0910–0645. Most reports are submitted using the Electronic Submissions Gateway (ESG), our centralized system for securely receiving electronic submissions. Reports may also be submitted via the Safety Reporting Portal (SRP), found at *https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=c16bcd94-42a8-4a68-9272-df4a62d8462c,* which is intended to streamline the process of reporting product safety issues to FDA using ''Rational Questionnaires.''

II. MedWatch Reporting Forms

A. MedWatch Form FDA 3500 (Voluntary Reporting for Health Professionals)

Form FDA 3500 is used by healthcare professionals as well as consumers to submit all reports not mandated by Federal law or regulation. Individual health professionals are not required to submit reports with the exception of certain adverse reactions following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1). Form FDA 3500 may be used to report serious adverse events, product problems, and product use errors and therapeutic failures. Reporting is supported for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and nonprescription (over-the-counter) human drug products marketed without an approved application. Form FDA 3500 may also be used to submit reports about tobacco products and dietary supplements.

B. MedWatch Form FDA 3500A (Mandatory Reporting)

Form FDA 3500A is used by manufacturers, user facilities, distributers, importers, and other respondents subject to mandatory reporting. Mandatory reporting of adverse events or product experiences is governed by statute and often codified in Agency regulations. Mandatory reporting of adverse reactions for human cells, tissues, and cellular- and tissue-based products is codified at 21 CFR 1271.350.

Reporting Under Sections 760 and 761 of the FD&C Act. The Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 (Pub. L. 109–462) amended the FD&C Act by adding sections 760 and 761 (21 U.S.C. 379aa and 379aa–1). Section 760 of the FD&C Act defines ''adverse event'' and ''serious adverse event'' for nonprescription drugs and prescribes specific reporting requirements, submission timing, and associated recordkeeping. The final guidance document entitled ''Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application,'' available for download at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-nonprescription-human-drug-products-marketed-without-approved,* discusses the statutory requirements and provides instructions on the reporting elements and the use of Form FDA 3500A. Similarly, section 761 of the FD&C Act defines ''adverse event'' and ''serious adverse event'' for dietary supplements and prescribes specific reporting requirements, submission timing, and associated maintenance of reporting records. The document entitled ''Guidance for Industry; Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act,'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-adverse-event-reporting-and-recordkeeping-dietary,* discusses these statutory requirements and provides instruction on the use and submission of Form FDA 3500A and discusses records required under section 761.

C. MedWatch Form FDA 3500B (Voluntary Reporting for Consumers)

Form FDA 3500B is a consumer-friendly version of Form FDA 3500 and is used for voluntary reporting. Respondents with access to the internet may visit our website at *https://www.fda.gov* and download Form FDA 3500B or contact us for assistance with completing and submitting the information. Form FDA 3500B is available in both English and Spanish.

III. FDA Safety Reporting Portal Rational Questionnaires

FDA currently receives several types of adverse event reports electronically via the SRP using rational questionnaires. These include:

1. Reportable Food Registry

Section 417 of the FD&C Act (21 U.S.C. 350f) defines ''reportable food'' and establishes reporting requirements for articles of foods (other than infant formula or dietary supplements) for which there is a reasonable probability that the use of, or exposure to, will cause serious adverse health consequences or death to humans or animals. We designed the reportable food registry (RFR) rational questionnaire to enable us to quickly identify, track, and remove from commerce an article of food (other than infant formula or dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause

serious adverse health consequences or death to humans or animals. FDA's Center for Food Safety and Applied Nutrition uses the information to help ensure that these products are quickly and efficiently removed from the market to prevent foodborne illnesses. Both mandatory and voluntary RFR reports must be submitted via the SRP.

2. Food, Infant Formula, and Cosmetic Adverse Event Reports

Rational questionnaires have also been developed for submitting adverse event reports for dietary supplements, food, infant formula, and cosmetics.

3. Animal Food Adverse Event and Product Problem Reports

Section 1002(b) of the FDA Amendments Act of 2007 (Pub. L. 110–85) directs the Secretary to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. We developed the Pet Food Early Warning System rational questionnaire as a user-friendly data collection tool, as well as a questionnaire for collecting voluntary adverse event reports associated with livestock food. Information collected in these voluntary adverse event reports contributes to our ability to identify adulteration of the livestock food supply and outbreaks of illness associated with livestock food. We use the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses.

4. Voluntary Tobacco Product Adverse Event and Product Problem Reports

The Center for Tobacco Products (CTP) has developed two voluntary rational questionnaires on the SRP. The first is utilized by consumers and concerned citizens to report tobacco product adverse event or product problems. A second rational questionnaire is used by tobacco product investigators in clinical trials with investigational tobacco products. Both CTP voluntary rational questionnaires capture tobacco-specific adverse event and product problem information from reporting entities such as healthcare providers, researchers, consumers, and other users of tobacco products.

In the **Federal Register** of June 30, 2021 (86 FR 34754), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received requesting clarification with regard to certain terms applicable to medical device reporting and exemptions from reporting. We note that information collection pertaining to medical device reporting is approved under OMB control number 0910–0437. The comment also discussed electronic reporting currently approved in OMB control number 0910–0645. Upon consideration of the comment and to help increase our organizational efficiency, we are consolidating the related reporting activities currently approved in OMB control number 0910–0645 into this single information collection request. Upon OMB approval of our request, we will discontinue OMB control number 0910–0645. In consideration of the comment, we have also proposed the following updates to the information collection instruments to help clarify information to be included in the corresponding data fields:

1. Revising the ''gender'' field to Forms FDA 3500, 3500A, and 3500B; to align with Centers for Disease Control and Prevention's use of these terms (*https://www.cdc.gov/hiv/clinicians/transforming-health/health-care-providers/collecting-sexual-orientation.html*), with the exception of the term ''Undifferentiated,'' which is included in the CDISC (Clinical Data Interchange Standards Consortium) language (premarket) standards (*https://www.cdisc.org/kb/articles/sex-and-gender*);

2. Revising Section B of Form FDA 3500 to the ''product problem'' field to include information about the root cause(s) of problem(s).

3. Revising instructions to clarify reporting instructions for paper-based reporting pertaining to adverse events associated with tobacco products; and

4. Revising instructions to clarify the term ''smoking'' refers to use of combusted products (cigarettes, cigars, pipes) to ''tobacco product use,'' which encompasses combusted and non-combusted tobacco products.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Reportable Foods Registry—Mandatory Reports	875	1	875	0.6 (36 minutes)	525
Reportable Foods Registry—Voluntary Reports	5	1	5	0.6 (36 minutes)	3
Food, Infant Formula, and Cosmetic Adverse Event Reports.	1,165	1.2	1,398	0.6 (36 minutes)	839
Voluntary Dietary Supplement Adverse Event Reports.	360	1.2	432	0.6 (36 minutes)	259
Mandatory Dietary Supplement Adverse Event Reports.	80	12	960	1	960
Animal Food: Pet Food Reports	2,024	1	2,024	0.6 (36 minutes)	1,214.40
Animal Food: Livestock Food Reports	25	1	25	0.6 (36 minutes)	15
Voluntary Tobacco Product Health Problem or Product Problem (*i.e.*, adverse experience) Reports to SRP (both questionnaires).	204	1	204	0.6 (36 minutes)	122
Mandatory Tobacco Product Health Problem or Product Problem (*i.e.*, adverse experience) Reports.	1	1	1	0.6 (36 minutes)	1
Total			5,924		3,938.4

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate of the number of respondents and the total annual responses is based primarily on mandatory and voluntary adverse event reports submitted to the Agency. The estimated total annual responses are based on initial reports. Followup reports, if any, are not counted as new reports. Based on our experience with

adverse event reporting, we assume it takes respondents 0.6 hour to submit a voluntary adverse event report via the SRP, 1 hour to submit a mandatory adverse event report via the SRP (except CTP, which estimates 0.6 hour), and 0.6 hour to submit a mandatory AER via the ESG (gateway-to-gateway transmission).

CTP used two data sources to estimate the reporting burden for tobacco product AEs. CTP researched the number of voluntary AE reports submitted to the center since the launch of the first tobacco questionnaire in the SRP in 2014. Our records indicated a total of 1,426 initial reports over the last 7 full calendar years. We used the total number of reports to average the number of yearly reports to 204. As referenced above, the premarket tobacco product application rule requires firms to submit adverse experience reports for tobacco products with marketing orders. The burden for these mandatory reports has been approved under OMB control number 0910–0879. For this collection, we have included 1 hour to acknowledge the inclusion under this collection. Therefore, the estimate for CTP voluntary and mandatory reports is expected to be 123 hours.

The submission of mandatory reports associated with drug products and biological drug products is accounted for and approved under OMB control number 0910–0230; the submission of mandatory reports associated with the Vaccine Adverse Event Reporting System is accounted for and approved under OMB control number 0910–0308; medical device report submissions are accounted for and approved under OMB control number 0910–0437; and the submission of mandatory reports associated with animal drug products is accounted for and approved under OMB control number 0910–0284.

Dated: March 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–05514 Filed 3–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0398]

Human Gene Therapy Products Incorporating Human Genome Editing; 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 document entitled ''Human Gene Therapy Products Incorporating Human Genome Editing; Draft Guidance for Industry.'' The draft guidance document provides recommendations to sponsors developing human gene therapy products incorporating genome editing (GE) of human somatic cells. Specifically, the guidance provides recommendations regarding information that should be provided in an investigational new drug (IND) application in order to assess the safety and quality of the investigational GE product, including information on product design, product manufacturing, product testing, preclinical safety assessment, and clinical trial design.

DATES: Submit either electronic or written comments on the draft guidance by June 14, 2022 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–2021–D–0398 for ''Human Gene Therapy Products Incorporating Human Genome Editing; Draft Guidance for Industry.'' 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.