• 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.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993–0002, 240–402–8926 or 301–796–2500, *dat.doan@fda.hhs.gov;* James Myers, 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; or Paul Kluetz, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2223, Silver Spring, MD 20993, 301–796–9567, *Paul.Kluetz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 6, 2024, FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry entitled ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' The Agency has received requests for a 30-day extension of the comment period. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the draft guidance.

FDA has considered the requests and is extending the comment period for 30 days, until March 6, 2025. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments on this draft guidance.

Dated: January 14, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01179 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3595]

Agency Information Collection Activities; Proposed Collection; Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification; Withdrawal of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a notice that was published in the **Federal Register** of October 18, 2023.

DATES: The notice is withdrawn on January 17, 2025.

FOR FURTHER INFORMATION CONTACT: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6206, Silver Spring, MD 20993–0002, 240–402–0978.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 18, 2023 (88 FR 71875), ''Agency Information Collection Activities; Proposed Collection; Comment Request: Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.'' FDA requested comment on the information collection associated with the proposed study entitled ''Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format to Minimize Misclassification.''

Under the Paperwork Reduction Act of 1995, Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

In the October 18, 2023, **Federal Register** notice, FDA proposed a new collection of information. However, FDA no longer intends to proceed with the proposed study due to circumstances and timing surrounding the execution of the study. Therefore, we are withdrawing the October 18, 2023 notice.

Dated: January 13, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01152 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5468]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration's Adverse Event and Product Experience Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA's

adverse event reports and product experience reports for FDA-regulated products.

DATES: Either electronic or written comments on the collection of information must be submitted by March 18, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 18, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2024–N–5468 for ''FDA's Adverse Event and Product Experience Reporting Program.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

FDA's Adverse Event and Product Experience Reporting Program

OMB Control Number 0910–0291—Extension

This information collection supports FDA laws and regulations governing adverse event reports and product experience reports for FDA-regulated products. The Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b, 355, 360i, 360l, 379aa, and 393) and the Public Health Service Act (42 U.S.C. 262) authorize FDA to collect adverse event reports and product experience reports from regulated industry and to monitor the safety of drugs, biologics, medical devices, and dietary supplements. These reporting and recordkeeping requirements are found in FDA regulations, discussed in Agency guidance, and included in Agency forms. Although there are no laws or regulations mandating postmarket reporting for medical foods, infant formula, cosmetics, or tobacco products, we encourage voluntary

reporting of adverse experiences associated with these products.

To facilitate both consumer and industry reporting of adverse events and experiences with FDA-regulated products, we developed the MedWatch program. The MedWatch program allows anyone to submit reports to FDA on adverse events, including injuries and/or deaths, as well as other product experiences associated with the products we regulate. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 329, 600, and 803 (21 CFR parts 310, 314, 329, 600, and 803), and specified in sections 503B, 760, and 761 of the FD&C Act (21 U.S.C. 353b, 379aa, and 379aa–1). Mandatory reporting of adverse events for human cells, tissues, and cellular- and tissue-based products (HCT/Ps) have been codified in § 1271.350 (21 CFR 1271.350). Other postmarketing reporting associated with requirements found in sections 201, 502, 505, and 701 (21 U.S.C. 321, 352, 355, and 371) of the FD&C Act and applicable to certain drug products with and without approved applications are approved under OMB control number 0910–0230. Mandatory reporting under part 803, associated with medical device products, using Form FDA 3500A, is approved under OMB control number 0910–0437.

Since 1993, mandatory adverse event reporting has been supplemented by voluntary reporting by healthcare professionals, patients, and consumers via the MedWatch reporting process. To carry out its responsibilities, the Agency needs to be informed when an adverse event, product problem, error with use of a human medical product, or evidence of therapeutic failure is suspected or identified in clinical use. When FDA receives this information from healthcare professionals, patients, or consumers, the report becomes data that will be used to assess and evaluate the risk associated with the product. FDA will take any necessary action to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

To implement these reporting provisions for FDA-regulated products (except vaccines) during their post-approval and marketed lifetimes, we developed the following three forms, available for download from our website or upon request to the Agency: (1) Form FDA 3500 may be used for voluntary (*i.e.,* not mandated by law or regulation) reporting by healthcare professionals; (2) Form FDA 3500A is used for mandatory reporting (*i.e.,* required by law or regulation); and (3) Form FDA 3500B, available in English and Spanish, is written in plain language and may be used for voluntary reporting (*i.e.,* not mandated by law or regulation) by consumers (*i.e.,* patients and their caregivers). Respondents to the information collection are healthcare professionals, medical care organizations and other user facilities (*e.g.,* extended care facilities, ambulatory surgical centers), consumers, manufacturers of biologicals, food products including dietary supplements and special nutritional products (*e.g.,* infant formula and medical foods), cosmetics, drug products or medical devices, and importers.

I. Use of Form FDA 3500, MedWatch—the Safety Information and Adverse Event Reporting Program (Voluntary Reporting)

This voluntary version of the form may be used by healthcare professionals to submit all reports not mandated by Federal law or regulation. Individual healthcare professionals are not required by law or regulation to submit reports to the Agency or the manufacturer, except for certain adverse events following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986. Reports for vaccines are not submitted via MedWatch or MedWatch forms but are submitted to the Vaccines Adverse Event Reporting System (VAERS; see *http://vaers.hhs.gov*), which is jointly administered by FDA and the Centers for Disease Control and Prevention.

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries (approved under OMB control number 0910–0437).

Under Federal law and regulation (section 761(b)(1) of the FD&C Act), a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act (21 U.S.C 342) after that product is marketed. Therefore, the Agency depends on the voluntary reporting by healthcare professionals and especially by consumers of suspected serious adverse events and product quality problems associated with the use of dietary supplements. All dietary supplement reports were originally received by the Agency on paper versions of Form FDA 3500 (by mail or fax). Today, electronic reports may be sent to the Agency via an online submission route called the Safety Reporting Portal at *http://www.safetyreporting.fda.gov/.* In that case, the Form FDA 3500 is not used.

Form FDA 3500 may be used to report to the Agency adverse events, product problems, product use errors, and therapeutic failures. The form is provided in both paper and electronic formats. Reporters may mail or fax forms to the Agency. A fillable PDF version of the form is available at *https://www.accessdata.fda.gov/scripts/medwatch/* or respondents can electronically submit a report via the MedWatch Online Voluntary Reporting Form at *https://www.accessdata.fda.gov/scripts/medwatch/.*

Reporting using Form FDA 3500 in paper form is supported for drugs, non-vaccine biologicals, medical devices, food products, special nutritional products, cosmetics, and non-prescription human drug products marketed without an approved application, and dietary supplements. Electronic reports for FDA products may be submitted to the Agency via an online submission route called the Safety Reporting Portal at *http://www.safetyreporting.fda.gov/.* Electronic reports for tobacco products may be submitted to the Agency via the tobacco questionnaire within the online Safety Reporting Portal at *http://www.safetyreporting.fda.gov/.*

II. Use of Form FDA 3500A, MedWatch for Use by User-Facilities, Importers, Distributors, and Manufacturers (Mandatory Reporting)

A. Drug and Biological Products

Sections 503B, 505(j), and 704 of the FD&C Act (21 U.S.C. 374) require that important safety information relating to all human prescription drug products be made available to FDA in the event it becomes necessary to take appropriate action to ensure protection of the public health. Mandatory reporting of adverse events for HCT/Ps is codified in § 1271.350. Consistent with statutory requirements, information is required to be submitted electronically and therefore we account for most all reports under OMB control number 0910–0230 to support electronic reporting to our MedWatch program. At the same time,

regulations are provided for waivers from the electronic submission requirements and we therefore account for paper-based reporting in this information collection.

B. Medical Device Products

Section 519 of the FD&C Act (21 U.S.C. 360i) requires manufacturers and importers of devices intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services (the Secretary) may by regulation reasonably require assuring that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Device Act of 1990 (Pub. L. 101–629), signed into law on November 28, 1990, amends section 519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under part 803. Part 803 mandates the use of Form FDA 3500A for reporting to FDA on medical devices. Mandatory reporting associated with medical device products using Form FDA 3500A is approved under OMB control number 0910–0437.

C. Dietary Supplements

Section 502(x) of the FD&C Act implements the requirements of The Dietary Supplement and Nonprescription Drug Consumer Protection Act, which became law (Pub. L. 109–462) on December 22, 2006. These requirements apply to manufacturers, packers, and distributors of nonprescription human drug products marketed without an approved application. The law requires reports of serious adverse events to be submitted to the Agency by manufacturers of dietary supplements.

Electronic reports for dietary supplements may be submitted using the Safety Reporting Portal at *http://www.safetyreporting.fda.gov/.* Paper-based dietary supplement reports may be submitted using the MedWatch Form FDA 3500A.

III. Use of Form FDA 3500B, MedWatch Consumer Voluntary Reporting

This voluntary version of the form may be used by consumers, patients, or caregivers to submit reports not mandated by Federal law or regulation. Individual consumers, patients, or caregivers are not required by law or regulation to submit reports to the Agency or the manufacturer. FDA supports and encourages direct reporting to the Agency by consumers of suspected adverse events and other product problems associated with human medical products, food, dietary supplements, and cosmetic products, and invite these respondents to visit our website at *https://www.fda.gov/safety/report-problem-fda* for more information. Since the inception of the MedWatch program in July 1993, the program has been promoting and facilitating voluntary reporting by both the public and healthcare professionals. FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free phone number or the MedWatch website on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Pub. L. 107–109).

Section 906 of the FDA Amendments Act (FDAAA) amended section 502(n) of the FD&C Act, mandating that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *https://www.fda.gov/medwatch,* or call 1–800–FDA–1088.'' Most private vendors of consumer medication information, which is the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report ''side effects'' to FDA and provide contact information to permit MedWatch reporting.

Form FDA 3500B, first made available in 2013, was tailored for consumers and has been written in plain language to conform with the Plain Writing Act of 2010 (Pub. L. 111–274) (*https://www.govinfo.gov/content/pkg/PLAW-111publ274/pdf/PLAW-111publ274.pdf*), and has evolved with input from human factors experts, from other regulatory agencies, and with extensive input from consumer advocacy groups and the public. It is used to report adverse events, product problems, product use errors, and problems after switching from one product maker to another maker to the Agency. The form is available in Spanish at *https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda,* and since 2021, has been available to upload electronically at *https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.spanish. The form is* provided in both paper and electronic formats. Respondents may submit reports by mail or fax to the Agency, or electronically submit a report via the MedWatch Online Voluntary Reporting Form at *https://www.accessdata.fda.gov/scripts/medwatch/.* A fillable PDF version of the form, available at *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf,* may be downloaded, completed, and mailed or faxed to the Agency. Reporting is supported for drugs, non-vaccine biologicals, medical devices, food products, special nutritional products, cosmetics, and non-prescription human drug products marketed without an approved application. The paper form may also be used to submit reports about dietary supplements. Electronic reports for dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal at *https://www.safetyreporting.fda.gov/.*

IV. Use of Form FDA 3800, Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to FDA. Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances: food manufacturers, processors, packers, and holders; researchers; an applicant of an approved drug product or a manufacturer; distributor or packer listed on the label of any marketed drug product; drug manufacturers, sponsors, sponsor-investigators of investigational drugs and biologics; dietary supplement manufacturers, packers, and distributors; and tobacco product manufacturers.

Others, including healthcare providers, public health officials, and other professionals, as well as consumers and concerned citizens, may voluntarily submit reports if they encounter safety issues with a product and/or harmful effects that they believe are related to a product. The information collection includes the following Agency forms, available electronically, via the Safety Reporting Portal:

- Center for Veterinary Medicine (CVM)—Voluntary reporting of adverse events and product problems involving pet food or livestock food. Section 1002(b) of the FDAAA directed 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 pet and livestock food. Information collected in these voluntary adverse event reports contribute to CVM's ability to identify adulteration of the pet and livestock food supply and outbreaks of illness associated with pet and 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.

- Center for Tobacco Products (CTP)—Voluntary Tobacco Product Health Problem or Product Problem Reports (*i.e.,* Adverse experience reports). Voluntary adverse experience reports have been collected from consumers/concerned citizens and healthcare professionals via the SRP's Tobacco Problem Report (TPR) questionnaire since January 10, 2014, from tobacco product manufacturers via the SRP TPR since June 10, 2016, and from researchers engaged in clinical trials using investigational or legally marketed tobacco products via the SRP Tobacco Investigator Report (TIR) questionnaire since June 10, 2016.
- CTP—Mandatory Tobacco Product Health Problem or Product Problem Reports (*i.e.,* Adverse experience reports). On October 5, 2021 (86 FR 55300), FDA published a final rule entitled ''Premarket Tobacco Product Applications and Recordkeeping Requirements.'' The rule establishes regulatory definitions (21 CFR 1114.3) for adverse experience, serious adverse experience, and unexpected adverse experience associated with tobacco product use. The final rule, in effect since November 4, 2021, requires premarket applicants (manufacturers of new tobacco products) who receive marketing granted orders to report all serious and unexpected adverse experiences associated with the tobacco product (21 CFR 1114.41(a)(2)) that have been reported to the applicant or of which the applicant is aware, to the SRP or in another manner designated by FDA, within 15 calendar days of their awareness.

V. Proposed Modifications to Existing Forms 3500, 3500A, and 3500B

A. General Changes

The proposed modifications to Form FDA 3500, Form FDA 3500A, and Form FDA 3500B (English and Spanish) reflect changes that will bring the forms into conformity, since the previous authorization in 2022, with current regulations, rules, and guidances. The proposed extension to Form FDA 3500, Form FDA 3500A, and Form FDA 3500B will only have changes in the form instructions to provide clarity of reporting. The proposed changes fall into one of three categories: (1) regulatory driven revisions, (2) work improvements for the Center, and (3) report processing improvements. Formatting modifications are being proposed to several fields to enhance the quality, utility, and clarity of the information. We also propose to update the mailing address to Attn: MedWatch Program, White Oak Campus, Building 22, G0207, 10903 New Hampshire Ave., Silver Spring, MD 20993.

B. Changes Proposed for Form FDA 3500

Throughout the form, we propose to add calendar functionality to all date fields for uniformity and standardization of date format.

In the header, we propose to specify the intended reporters at the top of the form (*i.e.,* Health Professional Voluntary Reporting). In section A, we propose to revise ''Undifferentiated'' to ''Intersex'' in field 3a; combine the ''Ethnicity'' (field A5) and ''Race'' (field A6) fields as outlined in the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) issued on March 29, 2024; and add new text ''What is your race and/or ethnicity? Select all that apply.''

The selections will also include descriptions of each category. The data fields include the following:

- American Indian or Alaska Native—*For example, Navajo Nation, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana, Native Village of Barrow Inupiat Traditional Government, Nome Eskimo Community, Aztec, Maya, etc.*
- Asian—*For example, Chinese, Asian Indian, Filipino, Vietnamese, Korean, Japanese, etc.*
- Black or African American—*For example, African American, Jamaican, Haitian, Nigerian, Ethiopian, Somali, etc.*
- Hispanic or Latino—*For example, Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan, etc.*
- Middle Eastern or North African—*For example, Lebanese, Iranian, Egyptian, Syrian, Iraqi, Israeli, etc.*
- Native Hawaiian or Pacific Islander—*For example, Native Hawaiian, Samoan, Chamorro, Tongan, Fijian, Marshallese, etc.*
- White—*For example, English, German, Irish, Italian, Polish, Scottish, etc.*

In section B, we propose to reorder the outcomes attributed to the adverse events list so that ''Other Serious or Important Medical Events'' appears as the last choice of the outcomes listed in field B2, and add a field for reference ranges in the ''Relevant Test/Laboratory Data'' section (field B6).

In section C, we propose to add a field for ''Where (*e.g.,* website, pharmacy/store/state of purchase) was the suspect product obtained?'' and ''When (date) was the suspect product obtained?''

In section D, we propose to remove ''This report involves cosmetic, dietary supplement, food/medical food, and other.'' Cosmetic will now be captured under the ''Product Type'' section field D5.

We propose to add ''Usage Dates'' after ''Treatment Dates/Therapy Dates'' and add ''Usage'' after ''Treatment'' and ''Therapy'' in field D3. We propose to revise the ''Product Type'' section (field D5) as follows: (Dietary supplement and Food/medical food selections will be removed. Adverse events involving these products should be submitted through the Safety Reporting Portal)

- ○ Drug or Biologic
  - ■ Brand
  - ■ Generic or Biosimilar
  - ■ Over-the Counter (OTC)
  - ■ Compounded product (by a Pharmacy or an Outsourcing Facility)
- ○ Cosmetic
  - ■ Cosmetic for professional use only
  - ■ Cosmetic sold on a retail basis
- ○ Cannabinoid Hemp Products (such as products containing CBD)
- ○ Other

In section E, we propose to interchange the fields 2a and 2b so that ''Procode'' will now appear in field 2a and ''Common Device Name'' will appear in field 2b.

In section G, we propose to add a field entitled ''Packer'' to the list under ''Also Reported To'' in field G4.

In the ''Advice about Voluntary Reporting'' section, we propose to remove ''Special nutritional products (dietary supplements, medical foods, infant formulas)'' and ''Food (including beverages and ingredients added to foods'' and add ''If your report involves a health problem or product problem with foods or special nutritional products such as infant formulas, dietary supplements, or medical foods'', go to *https://www.safetyreporting.fda.gov* or call 1–888–723–3366 to report.

We propose to revise ''If your report involves a health problem or a product

problem with a tobacco product, go to *https://www.safetyreporting.fda.gov* or call 1–877–287–1363 to report.'' to ''If your report involves a health problem or a product problem with a tobacco product, including e-cigarettes (nicotine-containing vapes) or nicotine pouches, go to *https://www.safetyreporting.fda.gov* or call 1–877–287–1363 to report.''

C. Changes Proposed for Form FDA 3500A

Throughout the form, we propose to add calendar functionality to all date fields for uniformity and standardization of date format.

In the header, we propose to revise ''For use by user-facilities, importers, distributors and manufacturers'' to ''For use by user-facilities, importers, distributors, manufacturers and packers.'' We propose to remove the header ''FDA USE ONLY'' and revise the ''Exemption/Variance #'' field to ''Exemption/Variance/Alternative #.''

In section A, we propose to revise ''Undifferentiated'' to ''Intersex'' in field 3, combine the ''Ethnicity'' (field A5) and ''Race'' (field A6) fields as outlined in the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) issued on March 29, 2024, and propose to add the new text ''What is your race and/or ethnicity? Select all that apply.'' The selections will also include descriptions of each category.

The data fields include the following: combine the ''Ethnicity'' (field A5) and ''Race'' (field A6) fields as outlined in the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) issued on March 29, 2024 and add ''What is your race and/or ethnicity? Select all that apply.'' The selections will also include descriptions of each category.

The data fields include:

- *American Indian or Alaska Native—For example, Navajo Nation, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana, Native Village of Barrow Inupiat Traditional Government, Nome Eskimo Community, Aztec, Maya, etc.*
- *Asian—For example, Chinese, Asian Indian, Filipino, Vietnamese, Korean, Japanese, etc.*
- *Black or African American—For example, African American, Jamaican, Haitian, Nigerian, Ethiopian, Somali, etc.*
- *Hispanic or Latino—For example, Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan, etc.*
- *Middle Eastern or North African—For example, Lebanese, Iranian, Egyptian, Syrian, Iraqi, Israeli, etc.*
- *Native Hawaiian or Pacific Islander—For example, Native Hawaiian, Samoan, Chamorro, Tongan, Fijian, Marshallese, etc.*
- *White—For example, English, German, Irish, Italian, Polish, Scottish, etc.*

In section B, we propose to reorder the outcomes attributed to adverse events list so that ''Other Serious or Important Medical Events'' appears as the last choice of the outcomes listed in field B2, add ''Describe Event or Problem'' on page 1 and add ''Describe Event or Problem (continued)'' on page 2 (field B5), and add a field for reference ranges in the ''Relevant Test/Laboratory Data'' section (field B6)

In section C, we propose to revise the ''Name, Strength, Manufacturer/Compounder'' field under ''Manufacturer/Compounder Name'' to include a new field for ''FEI # for cosmetics''. This revision applies to ''Suspect Product #1'' and ''Suspect Product #2.'' (field C1). We propose to revise ''Usage Dates'' after ''Treatment Dates/Therapy Dates'' and add ''Usage'' after ''Treatment'' and ''Therapy.'' (field C4).

We propose to revise the ''Product Type'' section (field C6) as follows (applies to Suspect Product #1 and Suspect Product #2):

○ Drug or Biologic
  ■ Brand
  ■ Generic or Biosimilar
  ■ Over-the Counter (OTC)
  ■ Compounded product (by a Pharmacy or an Outsourcing Facility)
○ Cosmetic
  ■ Cosmetic for professional use only
  ■ Cosmetic sold on a retail basis
○ Other

In section D, we propose to interchange fields 2a and 2b. ''Procode'' will now appear in field 2a and ''Common Device Name'' will appear in field 2b.

In section F, we propose to revise the ''User Facility or Importer Name/Address'' field to ''User Facility or Importer Name/Address/Email'' (field F3), add the two selections ''Initial'' and ''Follow-up #____.'' with checkboxes in the ''Type of Report'' field (field F7), and delete the ''Date of This Report (01–JAN–1900)'' field (field F8). This information is requested in ''Report Sent to FDA?'' (field F11) or ''Report Sent to Manufacturer?'' (field F13).

In section G, we propose to revise ''Contact Office (and Manufacturing Site for Devices)'' or ''Compounding Outsourcing Facility'' to ''Contact Office (and Manufacturing Site for Devices)'' or ''Compounding Outsourcing Facility or Responsible Person'' (field G1), revise ''Use Facility'' to ''User Facility'' in the ''Report Source'' field (field G2), revise ''Date Received by Manufacturer (01–JAN–1900)'' to ''Date Received by Manufacturer (01–JAN–1900)'' or ''Responsible Person'' (field G3), revise ''ANDA #'' to ''ANDA/Pre-ANDA #.'' (field G4), revise ''Periodic'' to ''Non-expedited (periodic)'' under ''Type of Report'' field (field G6), and revise ''If action reported to FDA under 21 U.S.C. 360i(g), list correction/removal reporting number:'' to ''If action reported to FDA under 21 U.S.C. 360i(g), list FDA-assigned recall number or include a statement.'' (field H9)

VI. Changes Proposed for Form FDA 3500A Instructional Supplement

The FDA Form 3500A instructional supplement will be revised to correct grammatical errors and to clarify reporting instructions. In addition to these changes, the FDA Form 3500A instructional supplement will include revisions based on the Modernization of Cosmetics Registration Act of 2022.

A. General Instructions

The instructional supplement will include the following revisions specifically pertaining to cosmetics:

- Add ''or cosmetic product'' to ''If no suspect medical device is involved in a reported adverse event (*i.e.,* when reporting ONLY a suspect drug or, biologic) ONLY sections A, B, C, E, and G are to be filled out'';
- Remove ''or'' between drug and biologic;
- Add ''When reporting ONLY a cosmetic product, the sections and/or subsections/blocks that are not relevant to cosmetics should be left blank.'';
- Add ''Cosmetic Products: Responsible persons submitting serious adverse event reports for cosmetic products using Form FDA 3500A should include a copy of the label on or within the retail packaging of the cosmetic product, along with any information that can be provided to support the report, such as scans of labels and images of the serious adverse event. This may be submitted to FDA:'';
- Add ''via email at: *CosmeticAERS@fda.hhs.gov*''; and
- Add ''Or by mail to: FDA CDER Mail Center, Attn: Cosmetics MedWatch Reports. White Oak Campus, Building 22, G0207, 10903 New Hampshire Ave., Silver Spring, MD 20993''.

B. Front Page

For the front page, there are the following revisions:

- Add ''For cosmetic products, the User Facility/Importer Report # and Exemption/Variance # should be left blank in this section.'';
- Add ''(mfr report #): after ''Manufacturer report #'';
- Revise ''The manufacturer report number is also entered in block G9 on the back of the form'' to ''The manufacturer report number is also entered in block G8 on the back of the form.'';
- Add ''and for responsible persons for cosmetic products:'' to ''For drug and biologics manufacturers''; and
- Add ''that'' and ''or the responsible person to ''The ''mfr report #'' is the number the manufacturer chooses to uniquely identify the report, and should conform to any applicable regulations or guidances.''

C. Section B: Adverse Event or Product Problem

In section ''B1: Type of Report'' adverse event, include ''or cosmetic product'' to ''Any incident where the use of a product (drug or biologic, including human cell, tissue, or cellular or tissue-based product (HCT/P), at any dose, or a medical device (including in vitro diagnostic products), is suspected to have resulted in an adverse outcome in a patient.''

In section ''B2: Outcomes attributed to adverse event'', add ''and Cosmetic Products'' to'' Drugs and Biologics'', and include the regulatory reference ''21 CFR and section 605 of the FD&C Act, respectively.''

Under ''Disability or Permanent Damage,'' add ''or cosmetic products: Check if the adverse event resulted in a persistent or significant disability or incapacity.''

Under ''Congenital Anomaly/Birth Defect,'' remove ''medical.''

Under ''Other Serious (Important Medical Events),'' add ''*Cosmetic Products:* Check if the other categories are not applicable, such as when the adverse event results in an infection or significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance) other than as intended, under conditions of use that are customary or usual. Describe the outcomes in the actual narrative of the event in block B5.''

In section ''B4: Date of this Report,'' add '', and cosmetic products'' to ''For all mandatory reports filed for Medical Devices, Drugs, and Biologics, including human cells, tissues, and cellular and tissue-based products, enter the date the report is submitted to the FDA.''

In section ''B5: Describe Event or Problem,'' add ''For cosmetics, please indicate whether the product was for professional use only; describe the amount and frequency used; for which body parts the cosmetic product was used; and outcomes.''

D. Section C: Suspect Product(s)

In section ''C: Suspect Product (s),'' add ''For cosmetic products, fill out ONLY the blocks that are relevant to cosmetic products.''

In subsection C1, add the following after the ''Name, Strength, Manufacturer/Compounder'' instruction: ''For cosmetics: In the product name field, enter the statement of identity as such name appears on the label. If the product names in the listing are not unique, then also include distinguishing information for identification purposes. For example, please include a brand name or a code that the responsible person uses to distinguish the product. Such information may also be included, in addition to the product name, even when product names in the listing are unique. If you believe certain distinguishing information is confidential, please include that distinguishing information in parentheses.''

In subsection C1, add after the ''NDC# or Unique ID'' instruction: ''For cosmetic product(s), if available, the FDA Establishment Identifier (FEI) number obtained by the owner or operator of a facility(ies), of the facility that manufactured or processed the affected cosmetic product(s). FEI is also known as the Firm or Facility Establishment Identifier.''

In section ''C2: List Medical Products and Treatment Given at the Same time of the Event and Date,'' add ''For cosmetic reports include all related cosmetic products used at the same time.''

In section ''C3: Dose, Frequency & Route Used,'' add ''or the consumer'' after ''Describe how the product was used by the patient'' and add ''or number of applications, area of application'' in the parentheses after ''(*e.g.,* 500 mg QID orally or 10 mg every other day IV).''

In section ''C4: Treatment/Therapy Start and Stop Dates,'' add ''Usage'' to the ''C4: Treatment/Therapy Start and Stop Dates'' heading, and add ''treatment/therapy'' and ''or usage'' to the following sentence: ''Provide the date of administration was started (or best estimate) and the date stopped (or best estimate).''

In section C6, add ''Cosmetics for Professional Use Only, Cosmetics Sold on a Retail Basis,'' after ''Biosimilar,'' and before ''please check the best option that best fits this medical product.''

In section C7, add ''For cosmetic products, if available, include best by/use by date'' to the ''Expiration date'' after the current instruction.

E. Section G: All Manufacturers

In section G, add ''AND RESPONSIBLE PERSONS'' to the ''SECTION G: ALL MANUFACTURERS'' heading, ''or responsible persons (in case of cosmetic products)'' to the sentence, ''This section is to be filled out by all manufacturers,'' ''or cosmetic product'' to ''NOTE: If a drug, biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P),'' and ''(or responsible person in case of cosmetic product)'' to the ''manufacturer is reporting an adverse event in which no suspect medical device is involved, section G may be identically reproduced in place of section D on the front of the form so that a one-page form may be submitted.'' Also add ''For cosmetic products, fill out ONLY the blocks that are relevant to cosmetic products.''

In section, ''G1: Contact Office (and manufacturing site for devices) or Compounding Outsourcing Facility,'' add ''or Responsible Person (in case of cosmetic products)'' to ''Contact Office (and manufacturing site for devices) or Compounding Outsourcing Facility'' heading and add ''For cosmetic products, enter the information of the responsible person, which means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of the cosmetic product'' to the last sentence

In section ''G2: Report Source,'' add ''and Cosmetic Products'' to the sentence ''Drugs and Biologics, including HCT/Ps: a separate 3500A form must be completed for each identifiable patient described in the article or manuscript.'' Remove the text '', and'' between ''Drugs and Biologics.''

In section ''G3: Date received by manufacturer,'' add ''or responsible person (in case of cosmetic product)'' to the heading and add ''responsible person,'' to the following sentence: ''This means the date when the applicant, manufacturer, corporate affiliate, etc. receives information that an adverse event or medical device malfunction has occurred.''

In section G6: Type of Report under ''15-day,'' add the following: '', and cosmetic products'' to ''As specified in

the drug, biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P),'' ''or requirements'' to ''regulations for reports of serious and unexpected adverse events,'' change the ''Periodic'' label to ''Non-expedited (Periodic);'' and add ''For Cosmetic products, use this option for non-serious adverse event.''

Under Follow-up, add ''and cosmetic products'' to ''Follow-up reports on drugs, biologics, including HCT/Ps, should contain information that was submitted in the original report if the information is still correct.''

In section ''G7: Adverse Event Term(s),'' add '', and cosmetic products'' to ''[for use by drug, biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P),'' add ''(or responsible persons, in case of cosmetic products)'' to ''manufacturers only]''and remove ''or WHOART'' from the list of accepted standards.

In ''G8: Manufacturer Report Number,'' remove ''If submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer program transmission of a serious direct report, check the 'Other' box in block G2 and enter the FDA-assigned report number there'' and add ''For cosmetics: The manufacturer report number is the number the responsible person chooses to uniquely identify the report, and should conform to any applicable regulations or guidances. The submission will not be considered complete without this information. While FDA currently does not have a mandatory format for the Manufacturer Report Number for reporting cosmetic adverse events, we strongly encourage you to use a numbering system that provides unique information of the adverse event reported, such as the year, company name, and the case report number.''

VII. Changes Proposed for Form FDA 3500B

In the instructions section, we propose to make the following revisions:

- Under ''When do I use this form?'', revise the first bullet to ''You were hurt or had a bad side effect (including new or worsening symptoms) after taking a drug or using a medical device or product'' to ''You were hurt or had a bad side effect (including new or worsening symptoms) after using a product, drug, cosmetic or a medical device.''; and
- Add the word ''cosmetic'' after the word ''drug'' in the following bullets: ''You used a product, drug, cosmetic, or medical device incorrectly which could have or led to unsafe use'' and ''You noticed a problem with the quality of the product, drug, cosmetic, or medical device.''

Under ''Don't use this form to report:'', add the hyperlink for the Vaccine Adverse Event Reporting System, add descriptive language under tobacco products about e-cigarettes and nicotine pouches, remove the word cosmetic from the safety reporting portal language, and revise the hyperlink to the SRP. Also, add the following:

- Vaccines—report problems to the Vaccine Adverse Event Reporting System (VAERS) *http://vaers.hhs.gov.*
- Tobacco products, including e-cigarettes (nicotine-containing vapes) and nicotine pouches, report health or product problems to the Safety Reporting Portal (SRP) *https://www.safetyreporting.fda.gov/* or call 1–877–287–1363.
- Remove the word ''cosmetic'' from the last bullet—Food or dietary supplement products—report problems to the SRP *https://www.safetyreporting.fda.gov/.*

Under ''What types of products should I use this form for?'', add a comma between ''bone), allergenics'' in the first bullet, remove ''makeup'' in the third bullet, add a bullet for ''Cannabinoid Hemp Products (such as products containing CBD'', and remove the last bullet ''Foods (including beverages and ingredients added to foods).

Under ''Are there specific instructions for filling out the form?'', the first two bullets in this section will remain unchanged and new text will be added for the third and fourth bullets to read as follows:

- Including or attaching images of all sides of the product will help FDA review your report but is not required. Please do not send the products to FDA.
- The Global Unique Device Identification Database (GUDID) contains key device identification information submitted to FDA about medical devices that have Unique Device Identifiers (UDI). In collaboration with the National Library of Medicine, FDA has created a portal, called Access GUDID, to make device identification information in the GUDID available for everyone. For more information regarding the UDI#, refer to the UDI web page, *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.*

Under ''How can I contact the FDA if I have questions?'' add a following toll-free phone number for cosmetics: 1–888–723–3366, and add the following language to match that of the MedWatch Online application: ''If this is a medical emergency, please call 911'' and ''If you have a mental health crisis, please call 988.''

In section ''A—About the Problem,'' we propose to add a field for reference ranges in the ''Relevant Test/Laboratory Data'' section (field A5).

In section ''B—Product Availability,'' we propose to revise the question in field B2 from ''Do you have a picture of the product? (check yes if you are including a picture)'' to ''Do you have a picture of the product including product labels if reporting cosmetics? While not required, pictures of all sides of the product will help FDA review your report. (check yes if you are including pictures).''

Under the section, ''For a problem with a product, including,'' remove ''or make-up products'' from the fourth bullet and remove the following bullets 3 and 5: ''nutrition products, such as vitamins and minerals, herbal remedies, infant formulas, and medical food'' and ''foods (including beverages and ingredients added to foods).

Under the section ''For a health or product problem with a food, cosmetic, dietary supplement or tobacco product,'' remove the word ''cosmetic'' and revise the hyperlink to the SRP to *https://www.safetyreporting.fda.gov/.*

In section ''C: About the Products,'' we propose to remove ''This report is about,'' or field ''C1. Product'' field will be updated, and add a section for a second suspect product and design the two sections for suspect product on the same page to facilitate the addition of another page if the reporter needs to report more than two products.

For field C3, we propose to add ''usage'' after ''therapy.'' The revised language will be ''Check if therapy/usage is on-going.''

We propose to revise the field ''Product Type'' (field C5) as follows: ''(Note: Dietary supplement and Food/Medical Food selections will be removed. Adverse events involving these products should be submitted through the Safety Reporting Portal)

- Drug or Biologic
  - Brand
  - Generic or Biosimilar
  - Over-the Counter (OTC)
  - Compounded product (by a Pharmacy or an Outsourcing Facility)
- Cosmetic
  - Cosmetic for professional use only
  - Cosmetic sold on a retail basis
- Cannabinoid Hemp Products (such as products containing CBD
- Other

For field C12, revise instructions from ''How was it taken or used (for example,

by mouth, injection, or on the skin)?'' to ''How was it taken or used (for example, by mouth, injection, inhaled, or on the skin)?'', add a field for ''Purchase Date'', and add a field for ''Where (*e.g.,* website, pharmacy/store/state of purchase) was the suspect product obtained?'' and ''When (date) was the suspect product obtained?'' We propose addition of fields to capture ''Place of Purchase Name,'' ''web page/URL (if purchased online),'' and ''Place of Purchase City and State/Province.''

Under section ''D—About the Medical Device,'' we propose to add text to read as ''Unique Device Identifier (UDI) number—Please record all symbols, letters and numbers located under the barcode. An example of a UDI number can be found at *https://accessgudid.nlm.nih.gov/about-gudid#what-is-udi*'' for field D7.

Under section ''E—About the Person Who Had the Problem,'' we propose to revise ''Undifferentiated'' to ''Intersex'' in field 2a, add calendar functionality to field E4 (Date of Birth) for uniformity in reporting and to ensure correct reporting of date format, and combine the ''Ethnicity'' (field E6) and ''Race'' (field E7) fields as outlined in the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) issued on March 29, 2024. We propose to add new text ''What is your race and/or ethnicity? Select all that apply.'' The selections will also include descriptions of each category.''

The data fields include:

- *American Indian or Alaska Native—For example, Navajo Nation, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana, Native Village of Barrow Inupiat Traditional Government, Nome Eskimo Community, Aztec, Maya, etc.*
- *Asian—For example, Chinese, Asian Indian, Filipino, Vietnamese, Korean, Japanese, etc.*
- *Black or African American—For example, African American, Jamaican, Haitian, Nigerian, Ethiopian, Somali, etc.*
- *Hispanic or Latino—For example, Mexican, Puerto Rican, Salvadoran, Cuban, Dominican, Guatemalan, etc.*
- *Middle Eastern or North African—For example, Lebanese, Iranian, Egyptian, Syrian, Iraqi, Israeli, etc.*
- *Native Hawaiian or Pacific Islander—For example, Native Hawaiian, Samoan, Chamorro, Tongan, Fijian, Marshallese, etc.*
- *White—For example, English, German, Irish, Italian, Polish, Scottish, etc.*

Under section F, ''About the Person Filling Out This Form,'' we propose to change the title of the field from ''City and State/Province'' to ''City and State/Province (including your State/Province will help FDA review your report) for field F4, and under ''Send This Report by mail or fax,'' revise the mailing address to the following: Attn: MedWatch Program, White Oak Campus, Building 22, G0207, 10903 New Hampshire Ave., Silver Spring, MD 20993.

FDA welcomes comments from the public and interested parties on a proposed report concept.

VIII. Consumer Complaint Form

The consumer complaint form will be used by all Centers to facilitate reporting complaints and product problems from the public to FDA. The four required data elements (patient identifier, description of event or problem, product name, and reporter), demographic information, and contact information (phone number and/or email address) may be requested. This form will be available externally with the long-term goal to allow submission of streamlined reports online.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center or 21 CFR section and/or FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CBER/CDER, FDA 3500 (voluntary reporting)	58,711	1	58,711	0.66 (40 minutes)	38,749
CBER, FDA 3500A; 600.80; 1271.350 (mandatory reporting)	599	98	58,702	1.21	71,029
CBER, FDA 3500B	13,750	1	13,750	0.46 (28 minutes)	6,325
CDER, FDA 3500B	18,961	1	18,961	0.46 (28 minutes)	8,722
CDRH, FDA 3500 and FDA 3500B	15,304	1	15,304	0.46 (28 minutes)	7,040
CTP, FDA 3500	39	1	39	0.66 (40 minutes)	26
HFP, FDA 3500	7,442	1.061	7,895	0.66 (40 minutes)	5,211
HFP, FDA 3500A	1,659	1	1,659	1.21	2,007
Written requests for temporary waiver under § 329.100(c)(2)	1	1	1	1	1
Total					139,110

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
CBER = Center for Biologics Evaluation and Research
CDER = Center for Drug Evaluation and Research
CDRH = Center for Devices and Radiological Health
HFP = Human Foods Program
CTP = Center for Tobacco Products

The estimates in table 1 are based on current Agency data and our experience with the information collection.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN E-SUBMISSIONS INCLUDING VIA SRP [1]

FDA form 3800	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: Voluntary Pet Food Reports	1,401	1	1,401	0.6 (36 minutes)	841
Animal Food: Voluntary Livestock Food Reports	23	1	23	0.6 (36 minutes)	14
Voluntary Tobacco Product Health Problem or Product Problem (i.e., adverse experience) Reports to SRP (both questionnaires)	176	1	176	0.6 (36 minutes)	106
Mandatory Tobacco Product Health Problem or Product Problem (i.e., adverse experience) Reports 1114.41(a)(2)	3	6	18	0.6 (36 minutes)	11
Total			5,924		3,961

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

The number of respondents for the Voluntary Tobacco Product Health Problem or Product Problem Reports e-submissions has decreased from 204 to 176, according to an updated analysis.

Based on burden estimates associated with the Premarket Tobacco Product applications and Recordkeeping Requirements regulation, we have decreased the average burden per response from 1 hour to 36 minutes for ''1114.41(a)(2); Mandatory Tobacco Product Health Problem or Product Problem Reports.''

CVM reports a decrease in the number of submissions received over the last few years.

FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) has increased the number of direct safety reports from healthcare providers and consumers. Additionally, CDER mandatory reports Form FDA 3500A previously included in this information collection, are now reported in the approved information collection, OMB control number 0910–0230. However, increases in receipts of CBER mandatory reports have obscured any decrease in burden. Adverse event reports related to 21 CFR 310.305 from outsourcing facilities are also included in OMB control number 0910–0230 and decreases the total burden of this collection.

Based on updated data, the Center for Devices and Radiological Health (CDRH) has revised our estimate for forms FDA 3500 and FDA 3500B. Additionally, we have determined that the estimate previously reported in this information collection for mandatory reporting under part 803, associated with medical device products, using Form FDA 3500A, is redundant with our approved burden estimates in OMB control number 0910–0437 ''Medical Device Reporting (under part 803).'' We have therefore removed CDRH reporting via Form FDA 3500A from this information collection request and continue to account for its burden in OMB control number 0910–0437.

Based on Agency experience the Human Food Program's estimated burden for the information collection reflects an overall increase. We attribute this adjustment to an increase in the number of submissions we received over the last few years, due primarily to changes in the infant formula industry.

Therefore, the cumulative changes, both program changes which include form revisions, and adjustments reflecting fluctuations in submissions, as well as removing double-counted burden reflects and overall increase of 116,014 hours to the total burden for this information collection.

Dated: January 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01149 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5943]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on ''Tobacco Product Establishment Registration and Listing.''

DATES: Either electronic or written comments on the collection of information must be submitted by March 18, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be