representative from the government of Canada, one representative from the industry of Canada, one representative from the government of South Africa, and one representative from the industry of South Africa. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach To Establish an Acute Reference Dose (ARfD)

The VICH Steering Committee held a meeting in February 2015 and agreed that the draft guidance document entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)'' (VICH GL54) should be made available for public comment. This draft VICH guidance document is intended to address the nature and types of data that can be useful in determining an ARfD for residues of veterinary drugs, the studies that may generate such data, and how the ARfD may be calculated based on these data.

FDA and the VICH Expert Working Group will consider comments about the draft guidance document.

III. Significance of Guidance

This draft guidance, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD). 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.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Action of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

VI. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: May 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13105 Filed 5–29–15; 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 Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by July 1, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0291. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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 Medical Products Reporting Program OMB Control Number 0910–0291—Extension

I. Background

To ensure the marketing of safe and effective products, it is critical that postmarketing adverse outcomes and product problems are reported for all FDA-regulated human healthcare products, including drugs (prescription and nonprescription), biologics, medical devices, dietary supplements and other special nutritional products (*e.g.* infant formula and medical foods), and cosmetics. To facilitate reporting on human medical products (except vaccines) during their postapproval and marketed lifetimes, three forms (collectively known as the MedWatch forms) are available from the Agency. Form FDA 3500 is intended to be used for voluntary (*i.e.,* not mandated by law or regulation) reporting by healthcare professionals. Form FDA 3500B is written in plain language and is intended to be used for voluntary reporting (*i.e.,* not mandated by law or regulation) by consumers (*i.e.,* patients and their caregivers). Form FDA 3500A is used for mandatory reporting (*i.e.,* required by law or regulation). 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 then take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

Authorizing Statutes and Codified Regulations

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353b, 355, 360i, 360*l,* and 393) and the Public Health Service Act (42 U.S.C. 262) represent the statutory authority for the FDA to collect mandatory adverse event reports from regulated industry on medical products once approved for marketing to monitor the safety of drugs, biologics, medical devices, and dietary

supplements. There are no laws or regulations mandating the postmarket reporting for medical foods, infant formula, cosmetics, or tobacco products, and the reporting for these products is done voluntarily.

Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 (21 CFR 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, 803.56, and specified in sections 503B, 760, and 761 (21 U.S.C. 379aa and 379aa–1) of the FD&C Act. Mandatory reporting of adverse reactions for human cells, tissues, and cellular- and tissue-based products (HCT/Ps) has been codified in 21 CFR 1271.350.

II. Use of Form 3500 (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 health professionals are not required by law or regulation to submit reports to the Agency or the manufacturer 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). Reports for vaccines are not submitted via MedWatch or MedWatch forms, but are submitted to the Vaccines Adverse Event Reporting System (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.

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 health 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 previously received by the Agency on paper versions of Form FDA 3500 (or Form FDA 3500B) (by mail or fax). Currently, electronic reports may be sent to the Agency via an online submission route called the Safety Reporting Portal (*http://www.safetyreporting.hhs.gov/*). In that case, Form FDA 3500 (or Form FDA 3500B) is not used.

Form FDA 3500 may be used to report to the Agency serious adverse events, product problems, and product use errors and therapeutic failures. The form is provided in both paper and electronic formats. Reporters may mail or fax paper forms to the Agency (a fillable PDF version of the form is available at *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf*) or reporters may electronically submit a report via the MedWatch Online Voluntary Reporting Form (*https://www.accessdata.fda.gov/scripts/medwatch/*). Reporting is supported for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and non-prescription (over the counter (OTC)) human drug products marketed without an approved application. The paper form may also be used to submit reports about tobacco products and dietary supplements. Electronic reports for tobacco products and dietary supplements may be submitted to the Agency via an online submission route called the Safety Reporting Portal (*http://www.safetyreporting.hhs.gov/*).

III. Use of Form 3500B (Consumer Voluntary Reporting)

This voluntary version of the form may be used by consumers (*i.e.* patients and their caregivers) to submit reports not mandated by Federal law or regulation. Individual patients or their 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 serious adverse outcomes and other product problems associated with human medical products, (*http://www.fda.gov/Safety/ReportaProblem/default.htm*). Since the inception of the MedWatch program, launched in July 1993 by then FDA Commissioner David Kessler, the program has been promoting and facilitating voluntary reporting by both the general public and healthcare professionals. FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free phone number or the MedWatch Internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Pub. L. 107–109).

On March 25, 2008, section 906 of the Food and Drug Administration Amendments Act (Pub. L. 110–85) amended section 502(n) of the FD&C Act and mandated 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 *www.fda.gov/safety/medwatch,* or call 1–800–FDA–1088.''

Most private vendors of consumer medication information, 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 reporting via the MedWatch process.

Since 2013, FDA has made available Form FDA 3500B. It was proposed during the previous authorization in 2012 and is a version of Form FDA 3500 that is tailored for consumers and written in plain language (in conformance with the Plain Writing Act of 2010 (Pub. L. 111–274) *http://www.gpo.gov/fdsys/pkg/PLAW-111publ274/pdf/PLAW-111publ274.pdf*).

Form FDA 3500B evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies, and with extensive input from consumer advocacy groups and the general public. Form FDA 3500B may be used to report to the Agency adverse events, product problems, and product use errors. The form is provided in both paper and electronic formats. Reporters may mail or fax paper forms to the Agency (a fillable PDF version of the form is available at *http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf*) or electronically submit a report via the MedWatch Online Voluntary Reporting Form (*https://www.accessdata.fda.gov/scripts/medwatch/*). Reporting is supported for drugs, non-vaccine biologicals, medical devices, special nutritional products, cosmetics, and non-prescription OTC human drug products marketed without an approved application. The paper form may also be used to submit reports about tobacco products and dietary supplements.

Electronic reports for tobacco products and dietary supplements may be submitted to the Agency via an online submission route called the

Safety Reporting Portal (*http://www.safetyreporting.hhs.gov/*).

IV. Use of Form FDA 3500A (Mandatory Version)

A. Drug and Biological Products

In sections 505(b), 505(j) (21 U.S.C. 354(b) and (j)), 503B, and 704 (21 U.S.C. 374) of the FD&C Act, Congress has required that important safety information relating to all human drug products be made available to the FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to the FDA for enforcement of the FD&C Act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs) and 600 (biological products). Mandatory reporting of adverse reactions for HCT/Ps has been codified in § 1271.350.

B. OTC Monograph Drug Products and Dietary Supplements

Section 760 of the FD&C Act provides for mandatory safety reporting for non-prescription human drug products marketed without an approved application as described in the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109–462), which became law on December 22, 2006. The law requires manufacturers, packers, and distributors of nonprescription, OTC human drug products marketed without an approved application (OTC monograph drug products) to submit reports of adverse experiences from domestic sources. The law also requires reports of serious adverse events to be submitted to FDA by manufacturers of dietary supplements.

C. Postmarketing Safety Reports—Changes in Format Starting in June 2015

Current requirements specify that postmarketing adverse experience reports must be submitted on paper on Form FDA 3500A (or the Council for International Organizations of Medical Sciences) I form for serious, unexpected adverse experiences from a foreign source). For the last several years the Agency has accepted electronic submissions in lieu of the paper Form FDA 3500A on the condition they are submitted in a manner that the Agency can process, review, and archive. On June 10, 2014, the Agency issued a final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements'' (79 FR 33072) that requires electronic submission of all mandatory postmarketing safety reports, including individual case safety reports. Entities with mandatory reporting obligations under parts 310 and 314 (drugs) and 600 (biological products) and specified under section 760 of the FD&C Act must implement this rule within 1 year of the issuance date (by June 10, 2015). For more information, go to *http://www.gpo.gov/fdsys/pkg/FR-2014-06-10/pdf/2014-13480.pdf*.

D. 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 may, by regulation, reasonably be required to provide assurance that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Devices 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. The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), signed into law October 26, 2002, amended section 519 of the FD&C Act. The MDUFMA amendment (section 303) required FDA to revise the MedWatch forms to facilitate the reporting of information relating to reprocessed single-use devices, including the name of the re-processor and whether the device has been reused.

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

A. General Changes

The proposed modifications to Forms FDA 3500 and 3500A reflect changes that will bring the forms into conformation, since the previous authorization in 2012, with current regulations, rules, and guidances.

B. Changes Proposed for Form FDA 3500

Formatting modifications are proposed to several fields to enhance the clarity and utility of the information collected. In section A2, it is proposed that checkboxes for years, months, weeks, and days be added to permit clarity about the age of the patient. In section A4, it is proposed that checkboxes for pounds (lb) and kilograms (kg) be added to permit clarity about the patient's weight. To permit clarity and utility for the dates being reported, it is proposed that field labels and instructions be modified to ask the reporter to use the format DD–MMM–YYYY. A watermark will be added to the date fields to prompt the reporter to enter data using this format. This proposed change will reduce the data-entry burden for FDA by making the form more easily scanned by the optical character recognition (OCR) software used by the Agency. This change is proposed for all of the date fields on the form including: A2 (Date of Birth), B2 (Death), B3, B4, C (Returned to Manufacturer On), D7, E4 (Expiration Date), E6, and E7.

In recognition of OMB 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, and as part of FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (*http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf*) developed in response to the requirement in section 907 of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 (Pub. L.112–144), changes are proposed to the location and formatting of the fields containing data about the patient's race. It is proposed that race be deleted from the descriptor in section B, field B7, that requests ''Other Relevant History, Including Preexisting Medical Conditions (*e.g.* allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.).'' Instead, it is proposed that a new race and ethnicity field be added to section A, ''Patient Information.'' The proposed ethnicity field will be numbered 5a and state ''Ethnicity (Check single best answer)'' with corresponding checkboxes for ''Hispanic/Latino'' and ''Not Hispanic/Latino.'' Adjacent to this field, the ''Race'' field will be numbered 5b and state ''Race (Check all that apply).'' It will contain checkboxes for ''Asian,'' ''American Indian or Alaskan Native,'' ''Black or African American,''

''White,'' and ''Native Hawaiian or Other Pacific Islander.''

Changes are proposed to the location, formatting, and labeling of fields related to the suspect product and its availability for evaluation to allow the product's identifying information to be grouped in one place, and increase the likelihood that this information is entered. In section D, field D1 will be used to request data for ''Name and Strength,'' ''Manufacturer/Compounder,'' as well as ''Lot #,'' and ''NDC # or Unique ID #'' for up to two suspect medical products.

In 2013, the Drug Quality and Security Act (Pub. L. 113–54) added new section 503B to the FD&C Act, under which a compounder may elect to become an outsourcing facility by registering with FDA. Outsourcing facilities are required to report adverse events to FDA in accordance with the content and format requirements established through guidance or regulation under § 310.305. In addition to mandatory reporting, many adverse events related to compounded drugs are reported voluntarily by healthcare professionals and consumers. Therefore, FDA is proposing changes to the voluntary versions of the MedWatch forms (*i.e.* Forms FDA 3500 and 3500B) to improve the ability to rapidly identify reports involving compounded drugs. The existing field (section D, field D1) that contains the descriptor ''Manufacturer'' will be relabeled ''Manufacturer/Compounder.'' Correspondingly, a checkbox for ''Manufacturer/Compounder'' will be added to the existing field (section G, field G4) ''Also Reported to.'' It is proposed that a new field be added to the section entitled ''Suspect Products.'' The new field will be numbered and include a descriptor ''Is the Product Compounded?'' with corresponding checkboxes for ''Yes'' or ''No.''

The new field will also include a descriptor ''Is the Product Over-the-Counter'' with corresponding checkboxes for ''Yes'' or ''No.'' The instructions to the form will be updated accordingly. The form remains a three-page form with all the main data fields on page one, with instructions for use and a self-addressed, postage-paid return mailer on the reverse side of page one, and page three being a continuation page for additional information should reporters need extra space.

C. Changes Proposed for Form FDA 3500A

Formatting modifications are proposed to several fields to enhance the clarity and utility of the information collected. In section A2, it is proposed that checkboxes for years, months, weeks, and days be added to permit clarity about the age of the patient. In section A4, it is proposed that checkboxes for pounds (lb) and kilograms (kg) be added to permit clarity about the patient's weight. To permit clarity and utility for the dates being reported, it is proposed that field labels and instructions be modified to ask the reporter to use the format DD–MMM–YYYY. A watermark will be added to the date fields to prompt the reporter to enter data using this format. This proposed change will reduce the data-entry burden for FDA by making the form more easily scanned by the OCR software used by the Agency. This change is proposed for all of the date fields on the form including: A2 (Date of Birth), B2 (Death), B3, B4, C7, D4 (Expiration Date), D6, D7, D10 (Returned to Manufacturer on), F6, F8, F11, F13, G4, and H4.

In recognition of OMB's 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, and as part of FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (*http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf*) developed in response to the requirement in section 907 of FDASIA, changes are proposed to the location and formatting of the fields containing data about the patient's race. It is proposed that race be deleted from the descriptor in section B, field B7, that requests ''Other Relevant History, Including Preexisting Medical Conditions (*e.g.* allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.).'' Instead, it is proposed that a new race and ethnicity field be added to section A, ''Patient Information.'' The proposed ethnicity field will be numbered 5a, and state ''Ethnicity (Check single best answer)'' with corresponding checkboxes for ''Hispanic/Latino'' and ''Not Hispanic/Latino.'' Adjacent to this field, the ''Race'' field will be numbered 5b, and state ''Race (Check all that apply).'' It will contain checkboxes for ''Asian,'' ''American Indian or Alaskan Native,'' ''Black or African American,'' ''White,'' and ''Native Hawaiian or Other Pacific Islander.''

Changes are proposed to the location, formatting, and labeling of fields related to the suspect product and its availability for evaluation to allow the product's identifying information to be grouped in one place and increase the likelihood that this information is entered. For consistency and clarity, it is proposed that many of the fields in the suspect products sections on Forms FDA 3500 and 3500A be mirrored. For Form FDA 3500A, it is proposed that the current section C, field C1, ''Name (Give labeled strength & mfr/labeler),'' also be used to request data for ''Lot #'' and ''NDC # or Unique ID #.'' Section C, field C1 will be relabeled ''Name, Manufacturer/Compounder, Strength.'' Proposed field C1 will contain distinct areas for ''Name and Strength,'' ''Manufacturer/Compounder,'' ''NDC # or Unique ID #,'' and ''Lot #'' for up to two suspect products. Since the information will now be captured in proposed field C1, separate fields for ''Lot #'' and ''NDC #/Unique ID #'' (C6 and C9 from the current form) will not be needed. The currently numbered field C2, ''Dose, Frequency & Route Used,'' will be renumbered C3. It will also be reformatted to have three distinct areas for dose, frequency, and route, respectively, for up to two suspect products. Current field C3, ''Therapy Dates,'' will be renumbered C4, and current field C4, ''Diagnosis for Use,'' will be renumbered C5. Current field C5, ''Event Abated After Use Stopped or Dose Reduced,'' will be renumbered C9, and field C8, ''Event Reappeared After Reintroduction?'' will be renumbered C10. The field for expiration date will be renumbered C8, and the field for concomitant medical products and therapy dates (current field C10) will be renumbered C2.

As stated previously, in 2013, the Drug Quality and Security Act added new section 503B to the FD&C Act, under which a compounder may elect to become an outsourcing facility by registering with FDA. Outsourcing facilities are required to report adverse events to FDA in accordance with the content and format requirements established through guidance or regulation under § 310.305. To facilitate implementation of this mandatory reporting requirement, changes will need to be made to the existing Form FDA 3500A. It is proposed that a new field be added to section G1 that contains the descriptor ''Compounding Outsourcing Facility 503B?'' with a corresponding checkbox for ''Yes.'' It is also proposed that a new field be added to section C, ''Suspect Products.'' The new field will be numbered C6 and include a descriptor ''Is the Product Compounded?'' with corresponding checkboxes for ''Yes'' or ''No'' (for up to two suspect products). The instructions to the form will be updated accordingly.

In addition, a new field numbered C7 will be added and ''Is the Product Over-the-Counter?'' with corresponding

checkboxes for ''Yes'' or ''No'' (for up to two suspect products). The instructions to the form will be updated accordingly.

Additionally, for clarity, in section G, field G5, the area labeled ''(A)NDA #'' will be split into two separate areas—one for ''ANDA #'' and one for ''NDA #.''

D. Changes Proposed for Form FDA 3500B

For consistency, and to improve the quality of the data received, the changes being proposed on the voluntary Form FDA 3500 (for use by healthcare professionals) are also being proposed on the voluntary Form FDA 3500B (for use by consumers). Formatting modifications are being proposed to several fields to enhance the quality, utility, and clarity of the information. In section D, the field entitled ''Age (at time the problem occurred) or Birth Date'' will be separated into separate fields for age and date of birth. In the field for ''Age,'' checkboxes for years, months, weeks, and days will be added to permit clarity about the age of the patient. Similarly, for the field in section D labeled ''Weight,'' checkboxes for pounds (lb) and kilograms (kg) will be added to permit clarity about the patient's weight. The instructions will be modified accordingly. To permit clarity about the dates being reported, field labels and instructions will be modified to ask the reporter to use the format DD–MMM–YYYY. A watermark will be added to the field to prompt the reporter to respond using this format. This will also reduce the data entry burden by making the form more easily scanned by the OCR software used by FDA. All of the date fields on the form will be affected by this proposed change. These include section A (date the problem occurred, death), section B (expiration date, date the person first started taking or using this product, date the person stopped taking or using this product), section C (date the implant was put in, date the implant was taken out), section D (date of birth), and section E (today's date).

A formatting modification to the field in section D that is currently labeled ''Race'' is being proposed in recognition of OMB 1997 Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity, and as part of FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (*http://www.fda.gov/downloads/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf*) developed in response to the requirement in section 907 of FDASIA. It is proposed that the field be relabeled ''Race (Check all that apply)'' and contain checkboxes for ''Asian,'' ''American Indian or Alaskan Native,'' ''Black or African American,'' ''White,'' and ''Native Hawaiian or Other Pacific Islander.'' It is also proposed that the field contain an adjacent area labeled ''Ethnicity (Check single best answer)'' with corresponding checkboxes for ''Hispanic/Latino'' and ''Not Hispanic/Latino.''

As discussed previously in this notice, many adverse events related to compounded drugs are reported voluntarily by healthcare professionals and consumers. Therefore, FDA is proposing changes to the voluntary versions of Forms FDA 3500 and 3500B to improve the Agency's ability to rapidly identify reports involving compounded drugs. FDA proposes to add a field to section B with the label ''Is the Product Compounded?'' and corresponding checkboxes for ''Yes'' or ''No.'' FDA also proposes to add a field to section B with the label ''Is the Product Over-the-Counter'' with corresponding checkboxes for ''Yes'' or ''No.''

Finally, to improve clarity and to be consistent with Form FDA 3500, FDA proposes to reword the last field of section E that currently asks ''May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product?'' to ''If you do NOT want your identity disclosed to the manufacturer, place an 'X' in this box.''

Items that we proposed in the 60-day notice that have changed: The proposed change to Form FDA 3500 to merge sections C and D has been retracted; therefore, the sections will not be re-sequenced on Form FDA 3500. For the proposed new field ''Is product compounded or over-the-counter'' (proposed on Forms FDA 3500, 3500A and 3500B), the descriptor ''Check all that apply'' will be deleted and these will be broken out into two separate questions, in two separate fields, with corresponding ''Yes'' and ''No'' checkboxes for up to two suspect products. The proposal to add a new ''compounder'' checkbox to Form 3500 Field G4 has been retracted. Instead the existing manufacturer checkbox will be relabeled ''manufacturer/compounder.'' The proposal to add a new field ''Product Available for Evaluation?'' to the ''suspect products'' section of the Form FDA 3500A was retracted. The proposed changes outlined above reflect these differences. We have reviewed the name address field for Forms FDA 3500 and 3500A and believe data quality would be improved if separate fields for last name, first name, address, state, ZIP code, and Country were also included instead of one field labeled ''name and address'' to capture all of that information.

In the **Federal Register** of December 11, 2014 (79 FR 73591), FDA published a 60-day notice requesting public comment on the proposed collection of information. Four comments were received.

Comments Affecting All Three FDA Forms (3500, 3500A, 3500B)

(Comment 1) One commenter recommended the option of an ''unknown'' check box for race/ethnicity.

(Response) FDA disagrees with this comment as it is inconsistent with the OMB standards for the classification of Federal data on race and ethnicity.

(Comment 2) One commenter requested an implementation date of 18 months after publication of the finalized form.

(Response) FDA will allow sufficient time for implementation.

Comments Affecting FDA Forms 3500 and 3500A

(Comment 1) Section G Field 4 and Section C Field 6: We propose to add a third checkbox labeled ''unknown'' for when this type of information is not received. Rationale: This information may not be received.

(Response) FDA disagrees. G4 corresponds to ''Date Received by Manufacturer'' on Form FDA 3500A. This is a required element and the manufacturer should always have this information. C6 corresponds to Lot # on the existing Form FDA 3500A. If this information is unknown the field should be left blank.

(Comment 2) In Section A1: Along with Patient Identifier, in bracket (first, last) can be added for better identification.

(Response) FDA disagrees. Capturing this data may discourage people from submitting voluntary reports. The instructions for the form state ''Do not use the patient's name or social security number.''

(Comment 3) In Section A2, Age group can be added.

(Response) FDA disagrees. The WG believes that the two data elements proposed for age—Age with checkboxes for days, weeks, months, years, and date of birth in the format DD–MMM–YYYY are sufficient to capture this data.

(Comment 4) In Section A3, after selecting Female, a check box should populate for pregnancy with options Yes, No, UNK. Pregnancy can be removed from section B7.

(Response) FDA disagrees. The Agency believes pregnancy status is captured sufficiently well through existing field B7.

(Comment 5) In Section B1, if Product problem check box is selected then only a text box to enter NDC# should come as National Drug Code is required ONLY when reporting a drug product problem. It can be removed from C9.

(Response) FDA disagrees. Product problem is not limited to drug products, and may include medical devices, biologics, and other products which would not have an associated NDC number.

(Comment 6) In section B2, Hospitalization—initial or prolonged can be relabeled to only Hospitalization and can have three check boxes; Initial, Prolonged and Hospital discharge summary available. Reporter can select whichever is applicable.

(Response) FDA Disagrees. We encourage reporters to put more detail about the hospitalization in the narrative text.

(Comment 7) In section B5, Describe Event or Problem, along with individual event terms, seriousness criteria for each event should be populated, so that event-wise seriousness criteria can be identified.

(Response) FDA disagrees. An event is considered serious if it meets the regulatory definition, as outlined in §§ 310.305, 314.80, 600.80, 803.3, and 1271.

Comments Affecting Form FDA 3500

None.

Comments Affecting Form FDA 3500A

(Comment 1) Action taken with drug can be added in section C.

(Response) FDA disagrees. This information equates to product use stopped or dose reduced, which is already captured on Forms FDA 3500 and 3500A.

(Comment 2) We propose that the FDA require medical device adverse reporting use the MedDRA dictionary instead of the Patient Problem Codes. Rationale: Currently when reporting adverse events for medical devices, the current dictionary used is the ''Patient Problem Codes of the Center for Devices and Radiological Health.'' This dictionary is much smaller (~800 terms) than the widely used MedDRA dictionary used when reporting adverse events with drugs (~20.6K terms). Using the MedDRA dictionary in place of the Patient Problem Codes would allow for more accurate recording of patient adverse events.

(Response) FDA disagrees. FDA will continue to use Patient Problem Codes for medical devices instead of MedDRA coding. While the MedDRA dictionary is able to adequately capture adverse events with drugs, patient problem codes and device problem codes are more effective at capturing device related adverse events.

(Comment 3) Causality scale can be added in Section C.

(Response) FDA Disagrees. Causality is not assessed at the reporting level. Refer to §§ 310.305(g), 314.80(k), 600.80(k)(1), and 803.16.

(Comment 4) In section C10, Concomitant Medical Products and Therapy Dates (Exclude treatment of event), Dose of concomitant drugs should also be included.

(Response) FDA disagrees. Concomitant medical products are not limited to drug products, and may include medical devices, biologics, and other regulated products. As concomitant products are not suspected to be related to the adverse event, it is not necessary to capture the dose.

(Comment 5) In Section E1, along with Phone#, Email address can also be included.

(Response) FDA disagrees. Form FDA 3500A, section E already includes a field for email address, as does Forms FDA 3500, section G, and 3500B. However, we have reviewed the name address field for Forms FDA 3500 and 3500A and believe data quality would be improved if separate fields for last name, first name, address, state, ZIP code, and Country were also included instead of one field labeled ''name and address'' to capture all of that information.

Comments Affecting Form 3500B

(Comment 1) One commenter urged the inclusion of a Spanish version of Form FDA 3500B.

(Response) FDA agrees with the importance of communicating the benefits and risks of medical products to healthcare providers and patients, especially underrepresented populations, including those with limited English proficiency. FDA's language access plan (*http://www.fda.gov/ForConsumers/ByAudience/MinorityHealth/ucm412582.htm*) outlines some of the steps FDA is taking to improve communications with underrepresented populations. FDA's drug safety communications are currently translated into Spanish and are available at *http://www.fda.gov/Drugs/DrugSafety/ucm263010.htm*. FDA is also working to improve the quality of the data received in adverse event reports received directly from consumers. At this time, FDA plans to focus resources on improving data quality from English-language consumer reports before evaluating how to best handle product experience information from non-English speaking consumers.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA center/21 CFR section/FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research:					
Form FDA 3500	14,727	1	14,727	0.66 (40 minutes)	9,720
Form FDA 3500A (§§ 310.305, 314.80, 314.98, 600.80, 1271.350).	599	98	58,702	1.21	71,029
Form FDA 3500A (§ 310.305 outsourcing facilities).	50	2	100	1.21	121
Center for Devices and Radiological Health:					
Form FDA 3500	5,233	1	5,233	0.66 (40 minutes)	3,454
Form 3500A (§ 803)	2,277	296	673,992	1.21	815,530
Center for Food Safety and Applied Nutrition:					
Form FDA 3500	1,793	1	1,793	0.66 (40 minutes)	1,183
Form 3500A	1,659	1	1,659	1.21	2,007
Center for Tobacco Products Form FDA 3500	39	1	39	0.66 (40 minutes)	26

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

FDA center/21 CFR section/FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total
All Centers Form FDA 3500B	13,750	1	13,750	0.46 (30 minutes)	6,325
Total					909,395

Dated: May 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13102 Filed 5–29–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1798]

Patient-Focused Drug Development for Alpha-1 Antitrypsin Deficiency; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for Alpha-1 Antitrypsin Deficiency (AATD). Patient-Focused Drug Development is an FDA performance commitment under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to provide FDA with patients' perspectives on the impact on daily life of AATD. FDA also is seeking patients' perspectives on the available therapies for this disorder.

DATES: The public meeting will be held on September 29, 2015, from 9 a.m. to 3:30 p.m. Registration to attend the meeting must be received by September 15, 2015. Registration from those individuals interested in presenting comments as part of the panel discussions should be received by July 31, 2015. See the **SUPPLEMENTARY INFORMATION** section for instructions on how to register for the meeting. Submit either electronic or written comments by November 30, 2015.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for public meeting participants (non-FDA employees) is through Building 1, where routine security checks will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Barbara Kass, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 1125, Silver Spring, MD 20993, 240–402–6887, FAX: 301–595–1243, email: *PatientFocused_CBER@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected AATD as the focus of a public meeting under the Patient-Focused Drug Development initiative. This initiative involves obtaining a better understanding of patients' perspectives on the challenges posed by AATD and the impact of current therapies for this condition. The Patient-Focused Drug Development initiative is being conducted to fulfill FDA performance commitments that are part of the PDUFA reauthorization under Title I of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144). The full set of performance commitments is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA has committed to obtaining the patient perspective on 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefits that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the **Federal Register** (78 FR 21613) that announced the disease areas for meetings in fiscal years (FY) 2013–2015, the first 3 years of the 5-year PDUFA V timeframe. The Agency used several criteria outlined in the April 11, 2013, notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. FDA has initiated a second public process for determining the disease areas for meetings in FY 2016–2017 and published a notice in the **Federal Register** on October 8, 2014 (79 FR 60857). More information, including the list of disease areas and a general schedule of meetings, is posted on FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Purpose and Scope of the Meeting

The purpose of this Patient-Focused Drug Development meeting is to obtain input on the symptoms and other impacts that matter most to patients with AATD. FDA also intends to seek patients' perspectives on current approaches to treating this disorder. FDA expects that this information will come directly from patients, caregivers, and patient advocates.

Individuals with AATD have low serum levels of Alpha-1-Antitrypsin (AAT, also known as Alpha-1 proteinase inhibitor (A1–PI)) and increased risks of developing a form of chronic obstructive lung disease called emphysema and, less frequently, liver disease. Some AATD patients with emphysema have symptoms of asthma. There are different genetic forms of the disease, but even among people with the same genetic form and similar levels of AAT in their blood, there is tremendous diversity in