

Applicants must also demonstrate their plans for engaging in shared decision making activities with their beneficiaries. Applicants are required to submit to CMS general beneficiary data, the clinical indicators needed to calculate the 10-year ASCVD risk score, and the cardiovascular Physician Quality Reporting System (PQRS) measures as outlined in the RFA. Eligible practices will be selected on a first come, first served basis until all 720 spots have been filled. Applications must be submitted timely in the standard format outlined in the CVD Risk Reduction Model RFA in order to be considered for review. Applications that are not received in this format will not be considered for review.

For more specific details regarding the CVD Risk Reduction Model (including the RFA), we refer applicants to the informational materials on the Innovation Center Web site at: <http://innovation.cms.gov/initiatives/Million-Hearts-CVDRRM/>. Applicants are responsible for monitoring the Web site to obtain the most current information available.

III. Collection of Information Requirements

Section 1115A(d)(3) of the Social Security Act states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of the models under this section. Consequently, there is no need for this document to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: May 15, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-1804]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach To Establish an Acute Reference Dose; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #232 entitled “Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute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). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). 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.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 31, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance 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.

FOR FURTHER INFORMATION CONTACT:

Tong Zhou, Center for Veterinary Medicine (HFV-153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0826, Tong.Zhou@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #232 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). In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Six observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one

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 Act 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]

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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, 360l, 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