

presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This

preliminary information serves to expedite the prehearing conference and commits participation.

The respondents are individuals or households, State or local governments, not-for-profit institutions and

businesses, or other for-profit groups and institutions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| 21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|--------------|
| 10.30—Citizen Petition | 207 | 1 | 207 | 24 | 4,968 |
| 10.33—Administrative reconsideration of action | 4 | 1 | 4 | 10 | 40 |
| 10.35—Administrative Stay of Action | 5 | 1 | 5 | 10 | 50 |
| 10.85—Advisory Opinions | 4 | 1 | 4 | 16 | 64 |
| 12.22—Filing Objections and Requests for a Hearing on a Regulation or Order | 3 | 1 | 3 | 20 | 60 |
| 12.45—Notice of Participation | 4 | 1 | 4 | 3 | 12 |
| Total | | | | | 5,194 |

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

The burden estimates for this collection of information are based on Agency records and experience over the past 3 years.

Dated: December 4, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-28825 Filed 12-9-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1067]

Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products—Content and Format; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled “Patient Counseling Information Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.” The recommendations in this guidance are intended to assist applicants in developing the “Patient Counseling Information” section of labeling and to help ensure that this section of labeling is clear, useful, informative, and to the extent possible, consistent in content and format. This guidance finalizes the draft guidance issued on September 18, 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Jonas Santiago, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6348, Silver Spring, MD 20993-0002, 301-796-5346; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Patient

Counseling Information Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.” This guidance is intended to assist applicants in developing the Patient Counseling Information section of labeling required under 21 CFR 201.57(c)(18). Recommendations include the following: (1) How to decide what topics to include in the section, (2) how to present information within the section, and (3) how to format and organize section contents.

This guidance is one of a series of guidances FDA is developing, or has developed, to assist applicants with the content and format of labeling for human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3922), FDA published a final rule on labeling for human prescription drug and biological products. The final rule and additional guidances can be accessed at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm>. The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

This guidance finalizes the draft guidance issued on September 18, 2013 (78 FR 57394). FDA reviewed all received comments carefully during the finalization of the guidance. Other than clarifying edits, no changes of significance were made to the final version of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's

current thinking on the content and format of the Patient Counseling Information section of labeling for human prescription drug and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. 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>.

III. The Paperwork Reduction Act of 1995

This 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 201.56 and 201.57 have been approved under OMB control number 0910–0572.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: December 4, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0588]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Guidance for Industry on Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI #214) entitled “Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data” (VICH GL35). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to provide recommended standards to construct a single Adverse Event Report (AER) electronic message to transmit VICH GL42 contents to all member regions and Product Problem Reports (PPR) to FDA for veterinary medicinal products. Please note that VICH GL42 has been harmonized in GFI #188, “Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine.”

DATES: Submit either electronic or written comments on Agency guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), 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 guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Margarita Brown, Center for Veterinary Medicine (HFV–240), Food and Drug

Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9048, CVMAESupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

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 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, 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