and in foreign languages or in the older, classical literature where it is not available on computerized literature databases or in the major scientific reference databases, such as the National Library of Medicine's literature database, all of which increases the time of obtaining substantiation.

In the **Federal Register** of January 6, 2000 (65 FR 1000), FDA published a final rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body. FDA estimated that there were 29,000 dietary supplement products marketed in the U.S. (65 FR 1000 at 1045). Assuming that the flow of new products is 10 percent per year, then 2,900 new dietary supplement products will come on the market each year. The structure/function final rule estimated that about 69 percent of dietary supplements have a claim on their labels, most probably a structure/function claim (65 FR 1000 at 1046). Therefore, we assume that supplement manufacturers will need time to assemble the evidence to substantiate each of the 2,001 claims (2,900 × 69 percent) made each year. If we assume that the 2,001 claims are equally likely to be pre-existing widely established claims, novel claims, or pre-existing claims that are not widely established, then we can expect 667 of each of these types of claims to be substantiated per year. Table 1 of this document shows that the annual burden hours associated with assembling evidence for claims is 189,428 (the sum of 667 × 44 hours, 667 × 120 hours, and 667 × 120 hours).

Dated: May 26, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13813 Filed 6–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0067]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Drug Product Communications, as Used by the Food and Drug Administration

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 5, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title "Data to Support Drug Product Communications, as Used by the Food and Drug Administration." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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.

Data To Support Drug Product Communications, as Used by the Food and Drug Administration—(OMB Control Number 0910–NEW)

Testing of communication messages in advance of a communication campaign provides an important role in improving FDA communications as they allow for an indepth understanding of individuals' attitudes, beliefs, motivations, and feelings. The methods to be employed include individual indepth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and professional clinician focus group interviews. The methods to be used serve the narrowly defined need for direct and informal opinion on a specific topic and, as a qualitative research tool, have two major purposes:

- To obtain information that is useful for developing variables and measures for formulating the basic objectives of risk communication campaigns and
- To assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences.

FDA will use these methods to test and refine its ideas and to help develop messages and other communications but will generally conduct further research before making important decisions, such as adopting new policies and allocating or redirecting significant resources to support these policies.

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers or Offices will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or health care professional perceptions and about use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, Medication Guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sale of medical products, and consumer and professional education.

In the **Federal Register** of February 8, 2011 (76 FR 6800), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Interviews/Surveys	19,822	1	19,822	14/60	4,757

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

Annually, FDA projects about 45 communication studies using the variety of test methods listed previously in this document. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: May 18, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13812 Filed 6–2–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0433] (formerly FDA–2003D–0474)

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Revised Guidance for Industry on "Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach To Establish a Microbiological ADI" (VICH GL–36(R)); Request for Comments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a draft revised guidance for industry (#159) entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI" (VICH GL36(R)). This draft revised guidance, which updates a final guidance on the same topic for which a notice of availability was published in the **Federal Register** of February 11, 2005, has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft revised VICH guidance was revised to include Appendix D—Supplement to Section 2 Regarding the Determination of the Fraction of Oral Dose Available to Microorganisms. This draft VICH guidance document is intended to provide guidance for assessing the human food safety of residues from veterinary antimicrobial drugs with regard to effects on the human intestinal flora.

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 revised guidance before it begins work on the final version of the revised guidance, submit either electronic or written comments on the draft revised guidance by August 2, 2011.

ADDRESSES: Submit written requests for single copies of the draft revised 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 draft revised guidance document.

Submit electronic comments on the draft revised 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: Silvia A. Pineiro, Center for Veterinary Medicine, (HFV–157), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240–276–8227, *Silvia.Pineiro@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 Approval 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 International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (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, the U.S. 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.

Four 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, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also