2000) and February 18, 1998 (expiring February 28, 2001), both under OMB No. 0970–0017. Also, new forms were approved by OMB No. 0970–0085 (Standard Interstate Forms), 0970–0152 (Lien and Subpoena Forms), and 0970–0154 (Wage Withholding Form). The final rule will update the State plan by removing the State plan preprint page for Section 3.12, Payment of Support thorough the IV–D agency or Other Entity. Section 314(c) of PRWORA repealed Section 466(c) of the Act. 45 CFR 302.57 is being removed by the final rule as it implemented Section 466(c). The requirements for State plan preprint page 3.12 are now covered by Section 3.14, Collection and Disbursement of Support Payments. The information collected on the State plan pages is necessary to enable OCSE to monitor compliance with the requirements in Title IV–D of the Social Security Act and implementing regulations.

Respondents: State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden per response	Total burden hours
State Plan for Child Support	54	1	43 min.	39

Estimated Total Burden Hours: 39.

ADDITIONAL INFORMATION: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W.; Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Attn: ACF Desk Officer.

Dated: July 13, 1999.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 99–18167 Filed 7–15–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2248]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidances on Efficacy of Anthelmintics: General Recommendations (#90), Efficacy of Anthelmintics: Specific Recommendations for Bovines (#95), Efficacy of Anthelmintics: Specific Recommendations for Ovines (#96), and Efficacy of Anthelmintics: Specific Recommendations for Caprines (#97); Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of four draft guidance documents entitled: ''Efficacy of Anthelmintics: General Recommendations (#90),'' ''Efficacy of Anthelmintics: Specific Recommendations for Bovines (#95),'' ''Efficacy of Anthelmintics: Specific Recommendations for Ovines (#96),'' and ''Efficacy of Anthelmintics: Specific Recommendations for Caprines (#97).'' These related draft guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). They are intended to standardize and simplify methods used in the evaluation of new anthelmintics submitted for approval to the European Union, Japan and the United States.

DATES: Submit written comments by August 16, 1999. FDA must receive comments before the deadline in order to ensure their consideration at the next VICH Committee.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm 1061, Rockville, MD 20852. Comments should be identified with the full title of the draft guidance documents and the docket number found in the heading of this document.

Copies of the draft guidance documents entitled ''Efficacy of Anthelmintics: General Recommendations,'' ''Efficacy of Anthelmintics: Specific Recommendations for Bovines,'' ''Efficacy of Anthelmintics: Specific Recommendations for Ovines,'' and ''Efficacy of Anthelmintics: Specific Recommendations for Caprines'' may be obtained on the Internet from the CVM home page at ''http://www.fda.gov/cvm/fda/TOCs/guideline.html''. Persons without Internet access may submit written requests for single copies of the draft guidances to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

FOR FURTHER INFORMATION CONTACT:

Regarding VICH: Sharon R. Thompson (HFV–3), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail: ''sthompso@cvm.fda.gov''.

Regarding the guidance documents: Thomas Letonja (HFV–130), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7576, e-mail: ''tletonja@cvm.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities, industry associations, and individual sponsors to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seeking scientifically based harmonized technical requirements for the development of pharmaceutical products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the registration of human pharmaceutical 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 registration of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH meetings are held under the auspices of the Office International des Epizooties (OIE). The VICH Steering Committee is composed of member representatives from the European Commission; the European Medicines Evaluation Agency; the European Federation of Animal Health; the Japanese Veterinary Pharmaceutical Association; the Japanese Ministry of Agriculture, Forestry and Fisheries; the U.S. Animal Health Institute; the U.S. FDA; and the U.S. Department of Agriculture.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/ New Zealand, one representative from industry in Australia/ New Zealand, one representative from MERCOSUR (Argentina, Brazil, Uruguay and Paraguay), and one representative from Federacion Latino-Americana de la Industria para la Salud Animal. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confédération Mondiale de L'Industrie de la Santé Animale (COMISA). A COMISA representative participates in the VICH Steering Committee meetings.

The VICH Steering Committee held meetings and agreed that the four draft guidance documents should be made available for public comment. On October 20 through 22, 1998, the Committee agreed to the draft guidance document entitled ''Efficacy of Anthelmintics: General Recommendations.'' On March 16 through 18, 1999, the Committee agreed on the three draft guidance documents entitled ''Efficacy of Anthelmintics: Specific Recommendations for Bovines,'' ''Efficacy of Anthelmintics: Specific Recommendations for Ovines,'' and ''Efficacy of Anthelmintics: Specific Recommendations for Caprines.''

The draft guidance entitled ''Efficacy of Anthelmintics: General Recommendations'' is intended to standardize and simplify the methods used for the effectiveness evaluation of new anthelmintics and generic copies for use in domesticated animals. Animal welfare will benefit by the elimination of duplicate studies, which will reduce the number of animals required for necessary studies. Likewise this will benefit the industry by reducing research and development costs. The three draft guidances entitled ''Efficacy of Anthelmintics: Specific Recommendations for Bovines,'' ''Efficacy of Anthelmintics: Specific Recommendations for Ovines,'' and ''Efficacy of Anthelmintics: Specific Recommendations for Caprines'' should be read in conjunction with the ''Efficacy of Anthelmintics: General Recommendations (EAGR).'' The guidances for bovines, ovines, and caprines are part of the EAGR, and the aim of these three draft guidances is to: (1) Be more specific for certain issues not discussed in the general guidance, (2) highlight differences with the EAGR on efficacy data recommendations, and (3) give explanations for disparities with the EAGR. Comments about the draft guidance documents will be considered by the FDA and the VICH Anthelmintic Working Group. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidances and publish them as future guidances.

These draft documents, developed under the VICH process, have been revised to conform to FDA's good guidance practices regulations (62 FR 8961, February 27, l997). For example, the documents have been designated ''guidance'' rather than ''guideline.'' Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as ''must,'' ''shall , '' and ''will'' in the original VICH documents have been substituted with ''should.'' Similarly, words such as ''requirement'' or ''acceptable'' or phrases such as ''minimum standards'' or ''minimum needed'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context. Additionally, the term(s) ''veterinary medicinal products'' and ''veterinary pharmaceuticals products'' may require revision to be consistent with product terms used in other VICH guidance documents.

These draft documents represent current FDA thinking on efficacy requirements for anthelmintic medicinal products. These documents do not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternate approaches may be used if they satisfy the requirements of applicable statutes, regulations, or both.

II. Comments

Interested persons should submit written comments on or before August 16, 1999 to the Dockets Management Branch (address above) regarding the guidance documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, except for Federal Holidays.

Dated: July 12, 1999.

Margaret M. Dotzel,

Acting Assoicate Commissioner for Policy Coordination.

[FR Doc. 99–18166 Filed 7–13–99; 12:06 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.