at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final guidance by January 17, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 8, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32056 Filed 12–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1629]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidances for Industry on ''Effectiveness of Anthelmintics: Specific Recommendations for Feline'' (VICH GL20) and ''Effectiveness of Anthelmintics: Specific Recommendations for Poultry'' (VICH GL21); 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 two draft guidances for industry (Nos. 113 and 114, respectively) entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Feline'' (VICH GL20) and ''Effectiveness of Anthelmintics: Specific Recommendations for Poultry'' (VICH GL21). These related draft guidance documents have been developed by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products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DATES: Submit written comments on the draft guidance documents by January 17, 2001, to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance documents entitled ''Effectiveness of Anthelmintics: Specific Recommendations Feline'' (VICH GL20) and ''Effectiveness of Anthelmintics: Specific Recommendations for Poultry'' (VICH GL21) 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 Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

You may submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the VICH: Sharon Thompson, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4514, e-mail: sthompso@cvm.fda.gov, or Carole R. Andres, Center for Veterinary Medicine (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–2977, e-mail: candres1@cvm.fda.gov.

Regarding the guidance documents: Thomas Letonja (HFV–135), 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 and industry associations to promote the international harmonization of regulatory recommendations. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical recommendations for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical recommendations 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 recommendations 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 recommendations 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; U.S. FDA; U.S. Department of Agriculture; Animal Health Institute; Japanese Veterinary Pharmaceutical Association; Japanese Association of Veterinary Biologics; and Japanese Ministry of Agriculture, Forestry, and Fisheries.

Two observers are eligible to participate in the VICH Steering Committee: One representative from the Government of Australia/New Zealand, and one representative from the industry in Australia/New Zealand. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the Confederation Mondiale de L'Industrie de la Sante Animale (COMISA). A COMISA representative also participates in the VICH Steering Committee meetings.

II. Guidance on Anthelmintics

The VICH Steering Committee held a meeting from June 14 through 16, 2000, and agreed that the two draft guidance documents entitled ''Effectiveness of Anthelmintics: Specific Recommendations for Feline'' (VICH GL20) and ''Effectiveness of Anthelmintics: Specific Recommendations for Poultry'' (VICH GL21) should be made available for public comment.

The two draft guidances, VICH GL20 and VICH GL21, should be read in conjunction with the ''Effectiveness of Anthelmintics: General Recommendations (EAGR)'' (64 FR 38445, July 16, 1999). The guidances for feline and poultry are part of the EAGR, and the aim of these two draft guidances is to: (1) Be more specific for certain issues not discussed in the general

guidance, (2) highlight differences with the EAGR on effectiveness data recommendation, 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 (65 FR 56468, September 19, 2000). 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 ''require'' or ''requirement'' have been replaced by ''recommendation'' or ''recommended'' as appropriate to the context.

These draft documents represent current FDA thinking on effectiveness recommendations for certain veterinary 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. An alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

III. Comments

These draft guidance documents are being distributed for comment purposes only and are not intended for implementation at this time. Interested persons should submit to the Dockets Management Branch (address above) written comments regarding the draft guidance documents by January 17, 2001. 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 draft guidance documents and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 8, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32057 Filed 12–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Tobacco Regulation for Substance Abuse Prevention and Treatment—45 CFR Part 96—(OMB No. 0930–0165; Extension, no change)—This final rule provides guidance to States regarding compliance with section 1926 of the Public Health Service Act (42 USC 300x–26) related to sale and distribution of tobacco to minors. The final rule implements section 1926 by specifying the content of the State's annual report on the provisions of the rule and application for block grant funds. The reporting burden shown below represents the average total hours to assemble, format and produce the information for the block grant provision on minors' access to tobacco, in accordance with the requirements of 45 CFR Part 96. These burden hours are counted towards the total burden for the annual Substance Abuse Prevention and Treatment Block Grant Application Format (OMB No. 0930–0080) for which separate approval is obtained.

45 CFR Citation	Number of responses	Respondents/ respondent	Hours/ response	Total hour burden
Annual report:				
96.122(f)	59	1	0	[1] 0
96.130(e)(1–3)	59	1	15	885
State Plan:				
96.122(g)(21)	0	0	0	[2] 0
96.130(e)(4–5)	59	1	14	826
96.130(g)	59	1	5	295
Total			34	2,006

[1] This section describes requirements for the first applicable, which has passed for all States. Therefore, no burden is associated with this section.

[2] This section duplicates the information collection language in section 96.130(e). The burden is shown for 96.130(e).

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Stuart Shapiro, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 11, 2000.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 00–32103 Filed 12–15–00; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under