

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 Comments about the draft guidance documents will be considered by the FDA and the VICH Anthelmintic Working Group.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 Similarly, words such as "require" or "requirement" have been replaced by "recommendation" or "recommended" as appropriate to the context.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These draft guidance documents are being distributed for comment purposes only and are not intended for implementation at this time. Interested persons should submit to the Dockets Management Branch (address above) written comments regarding the draft guidance documents by January 17, 2001.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 A copy of the draft guidance documents and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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.*

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### 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	<sup>1</sup> 0
96.130(e)(1-3) .....	59	1	15	885
State Plan:				
96.122(g)(21) .....	0	0	0	<sup>2</sup> 0
96.130(e)(4-5) .....	59	1	14	826
96.130(g) .....	59	1	5	295
<b>Total</b> .....	.....	.....	34	2,006

<sup>1</sup> This section describes requirements for the first applicable, which has passed for all States. Therefore, no burden is associated with this section.

<sup>2</sup> 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.*

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### 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