

Dated: March 30, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy,
Planning, and Evaluation, Centers for Disease
Control and Prevention (CDC).

[FR Doc. 01-8458 Filed 4-5-01; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Developmental Disabilities
Protection and Advocacy Statement of
Objectives and Priorities.

OMB No.: 0980-0270.

Description: Required by federal
statute and regulation. Each State
Protection and Advocacy System must

prepare and submit to public comment
a Statement of Objectives and Priorities
(SOP). The final version of this SOP for
the coming fiscal year is submitted to
ADD. The information in the SOP will
be aggregated into a national
prospective profile of where Protection
and Advocacy systems are going. It will
provide ADD with an overview of
program direction, and permit ADD to
track accomplishments against
objectives/targets, permitting the
formulation of technical assistance and
compliance with GPRA.

Respondents: State and Tribal
Government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A SOP	57	1	44	2,508
Estimated Total Annual Burden Hours				2,508

In compliance with the requirements
of Section 3506(c)(2)(A) of the
Paperwork Reduction Act of 1995, the
Administration for Children and
Families is soliciting public comment
on the specific aspects of the
information collection described above.
Copies of the proposed collection of
information can be obtained and
comments may be forwarded by writing
to the Administration for Children and
Families, Office of Information Services,
370 L'Enfant Promenade, SW.,
Washington, DC 20447, Attn: ACF
Reports Clearance Officer. All requests
should be identified by the title of the
information collection.

The Department specifically requests
comments on: (a) Whether the proposed
collection of information is necessary
for the proper performance of the
functions of the agency, including
whether the information shall have
practical utility; (b) the accuracy of the
agency's estimate of the burden of the
proposed collection of information; (c)
the quality, utility, and clarity of the
information to be collected; and (d)

ways to minimize the burden of the
collection of information on
respondents, including through the use
of automated collection techniques or
other forms of information technology.
Consideration will be given to
comments and suggestions submitted
within 60 days of this publication.

Dated: April 2, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01-8456 Filed 4-5-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Developmental Disabilities
Protection & Advocacy Program
Performance Report.

OMB No.: 0890-0160.

Description: Required by federal
statute. Each State Protection and
Advocacy System must prepare and
submit a Program Performance Report
for the preceding fiscal year of activities
and accomplishments and of conditions
in the State. The information in the
Annual Report will be aggregated into a
national profile of Protection and
Advocacy Systems. It will also provide
ADD with an overview of program
trends and achievements and will
enable ADD to respond to
administration and congressional
requests for specific information on
program activities. This information
will also be used to submit an Annual
Report to Congress as well as to comply
with requirements in GPRA.

Respondents: State and Tribal
Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
P&A PPR	57	1	44	2,508
Estimated Total Annual Burden Hours				2,508

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) was to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 2, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01-8547 Filed 4-5-01; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0131]

Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities." This guidance is intended to alert hospitals, nursing homes, and other health care facilities of the potentially fatal hazards of medical gas mixups. This guidance makes recommendations that will help

hospitals, nursing homes, and other health care facilities avoid the injuries and fatalities that have resulted from medical gas mixups.

DATES: Submit written comments on the guidance by July 5, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Duane S. Sylvia, Center for Drug Evaluation and Research (HFD-325), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-0095, ext. 8, Sylviad@cdcr.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled "Guidance on Hospitals, Nursing Homes, and Other Health Care Facilities." FDA has received reports during the past 4 years from hospitals and nursing homes involving 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but were receiving a different gas (e.g., nitrogen) that had been mistakenly connected to the oxygen supply system. As a result of these reports, FDA has decided to alert hospitals, nursing homes, and other health care facilities to the potentially fatal hazards associated with handling medical gases. The agency also is making recommendations that should help health care facilities avoid the tragedies that result from medical gas mixups.

Because of the potential danger to the public health of medical gas mixups, this guidance is being issued as a Level 1 guidance for immediate implementation, consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). As with other Level 1 guidances for immediate implementation, the agency is soliciting comments from the public. This guidance represents the agency's current thinking on how to avoid potentially fatal medical gas mixups. 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 written comments on the guidance to the Dockets Management Branch (address above). 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. The 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>.

Dated: March 29, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01-8474 Filed 4-5-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2248]

International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products (VICH); Final Guidances Entitled "Effectiveness of Anthelmintics: General Recommendations" (VICH GL7), "Effectiveness of Anthelmintics: Specific Recommendations for Bovine" (VICH GL12), "Effectiveness of Anthelmintics: Specific Recommendations for Ovine" (VICH GL13), and "Effectiveness of Anthelmintics: Specific Recommendations for Caprine" (VICH GL14); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of four final guidances for industry (Nos. 90, 95, 96, and 97) entitled "Effectiveness of Anthelmintics: General Recommendations" (EAGR) (VICH GL7), "Effectiveness of Anthelmintics: Specific Recommendations for Bovine" (VICH GL12), "Effectiveness of Anthelmintics: Specific