

Federal Register in accordance with 21 CFR 25.40(c).

Dated: August 25, 1997.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*

[FR Doc. 97-23588 Filed 9-4-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D-0268]

Draft Guidance for Industry on Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to November 14, 1997, the comment period on the agency's draft guidance for industry entitled "Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics." FDA published a notice of the availability of the draft guidance in the **Federal Register** of July 15, 1997 (62 FR 37925). FDA is extending the comment period in response to requests from the industry for additional time to review and comment on the draft guidance.

DATES: Written comments by November 14, 1997. General comments on agency guidance documents are welcomed at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Alan C. Schroeder, Center for Drug Evaluation and Research (HFD-570), 5600 Fishers Lane, Rockville, MD 20857, 301-827-1050.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 15, 1997, FDA published a notice announcing the availability of a draft guidance for industry entitled "Submission of Documentation in Drug Applications for

Container Closure Systems Used for the Packaging of Human Drugs and Biologics." The draft guidance discusses information on container closure systems used in packaging drugs that manufacturers should provide to FDA's Center for Drug Evaluation and Research in meeting regulatory requirements for new drug applications, abbreviated new drug applications, investigational new drug applications, abbreviated antibiotic applications, and supplements to these applications, and to the Center for Biologics Evaluation and Research in meeting requirements for biologics license applications and product license applications. The notice invited interested persons to submit written comments on the draft guidance by September 15, 1997.

FDA has received requests from several industry sources for additional time to review the draft guidance on container closure systems. FDA has considered these requests and is extending the comment period for 60 days.

Interested persons may, on or before November 14, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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 draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 29, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97-23586 Filed 9-4-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-211]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the

collection of information. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 C.F.R. Part 1320, in order for States to apply for funds to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children. States are able to use Title XXI funds for: (1) Establishing or expanding a separate child health insurance program, (2) expanding Medicaid coverage, or (3) through a combination of both. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result if normal clearance procedures are followed.

HCFA is requesting that OMB provide a Three Day review and a 180-day approval.

Type of Information Collection Request: New Collection; Title of Information Collection: State Child Health Plan; Form No.: HCFA-R-211; Use: This template will enable states to apply for funds to initiate and expand the provision of child health insurance to uninsured, low income children in a effective and efficient manner that is coordinated with other sources of health coverage for children; Affected Public: State, Local or Tribal Government; Number of Respondents: 56; Total Annual Responses: 56; Total Annual Hours: 8,960.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Laura Oliven, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 29, 1997.

William Broglie,

*HCFA Reports Clearance Officer, HCFA,
Office of Information Services, Information
Technology Investment Management Group,
Division of HCFA Enterprise Standards.*

[FR Doc. 97-23591 Filed 9-4-97; 8:45 am]

BILLING CODE 4120-03-P