

administrative proceedings for imposition of a civil penalty for violation(s) of Public Law 107-228. The authority to enforce penalty provisions of Public Law 107-228 will be delegated to the Office of Export Enforcement of the Bureau of Industry and Security, U.S. Department of Commerce, and/or the U.S. Department of Homeland Security.

In addition, the Census Bureau will address other issues in the forthcoming rulemaking process discussed above. Because the changes discussed above will result in a major revision of the Foreign Trade Statistics Regulations, we plan to use this as an opportunity to improve the regulations' clarity and readability. It is possible that we could make some additional changes to the rules as part of this process.

An additional purpose of this notice is to announce and request comment on the Census Bureau's intention, subject to agreement with the CBP and other federal agencies participating in the AES, to modify the AES Option 4 post-departure filing program. Currently, Option 4 is a method of post-departure filing that considers the trade community's business practices and also provides for an approval process that ensures that only the most compliant companies are approved for this method of filing. With Option 4 privileges, shipment information can be transmitted to the AES no later than ten working days from the date of exportation. (Refer to Foreign Trade Statistics Regulations, title 15, Code of Federal Regulations, part 30, sections 30.61 and 30.62, for information on AES filing Option 4.)

The Census Bureau also has had numerous discussions over the past several months with the trade community and several federal government agencies regarding a proposal to develop and implement the AES Filer Licensing and Permit Program. After consultation both internally and externally, the Census Bureau has decided not to move forward with the development and implementation of an AES filer licensing program concurrently with requiring full mandatory electronic filing of export information through the AES. However, the Census Bureau will continue to explore the need for an AES filer licensing program.

Executive Orders

This program notice has been determined to be not significant for

purposes of Executive Order (E.O.) 12866. This notice does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 13132.

Paperwork Reduction Act

Notwithstanding any other provisions of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a current valid Office of Management and Budget (OMB) control number. The forthcoming rules will contain a collection of information subject to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). In accordance with the PRA, this collection of information will be submitted to OMB for approval.

Program Change

The actual effective date of full AES mandatory filing requirements and implementation of the penalty provision regarding mandatory filing are dependent upon the publication and implementation of final regulatory amendments by the Census Bureau. Proposed and final rules defining the regulatory revisions that will be made to implement the legislation will be published in the **Federal Register**, as discussed above.

Dated: October 16, 2003.

Charles Louis Kincannon,
Director, Bureau of the Census.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 334

[Docket No. 1978N-036L]

RIN 0910-AA01

Laxative Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening until January 20, 2004, the administrative record for the rulemaking for over-the-counter (OTC) laxative drug products to accept comments and data concerning these drug products that have been filed with FDA's Division of Dockets Management, because the administrative record officially closed at various times during the course of this rulemaking. The administrative record will remain open until January 20, 2004, to allow for public comment on the comments and data being accepted into the rulemaking at this time. This action is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments and data by January 20, 2004.

ADDRESSES: Submit written comments and data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Mary S. Robinson, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has, on numerous occasions, received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record in a rulemaking proceeding. Under § 330.10(a)(7)(iii) (21 CFR 330.10(a)(7)(iii)), new data and information may be submitted within 12 months after publication of a tentative final monograph (TFM). Within 60 days after this 12-month period ends, comments on the new data and information may be submitted (see § 330.10(a)(7)(iv)). Under § 330.10(a)(10)(i), the administrative record closes at the end of this 60-day period.

FDA published a TFM on laxative drug products for OTC human use on January 15, 1985 (50 FR 2124). On a number of occasions since the TFM was published, FDA reopened the administrative record for this rulemaking for various reasons. (See table 1 of this document for reopening dates and reasons.)