DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99065]

National Institute for Occupational Safety and Health; Research on Young Worker Safety and Health Risks in Construction; Notice of Availability of Funds; Amendment

A notice announcing the availability of Fiscal Year 1999 funds for the Research on Young Worker Safety and Health Risks in Construction was published in the **Federal Register** on April 9, 1999, [Vol. 64 FR No. 68]. The notice is amended as follows:

On page 17392, first column, agency docket number should be changed to read [Program Announcement 99065].

On page 17392, third column, paragraph F, first paragraph, line 7, fourth word should read ''99065''.

On page 17392, third column, paragraph F, second paragraph, line 8, fourth word should read ''99065''.

On page 17393, third column, paragraph J, second paragraph, line 7, second word should read ''99065''.

Dated: April 13, 1999.

Diane D. Porter,

Acting Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–9740 Filed 4–16–99; 8:45 am]

BILLING CODE 4163–19–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1110]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; CGMP Regulations for Finished Pharmaceuticals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by May 19, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

CGMP Regulations for Finished Pharmaceuticals—21 CFR Parts 210 and 211 (OMB Control Number 0910–0139)—Reinstatement

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices (CGMP's) to ensure that such drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

FDA has the authority under section 701(a) of the act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the act regarding CGMP procedures for manufacturing, processing, and holding drugs and drug products. The CGMP regulations help ensure that drug products meet the statutory requirements for safety and have their purported or represented their purported or represented identity, strength, quality, and purity characteristics. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to protect public health and safety.

Although CGMP must be current in the industry, a practice need not be widely prevalent providing such practice is both feasible and valuable in ensuring drug quality. CGMP requirements establish accountability in the manufacturing and processing of drug products, provide for meaningful FDA inspections, and enable manufacturers to improve the quality of drug products over time. The recordkeeping requirements also serve preventive and remedial purposes and provide crucial information if it is necessary to recall a drug product.

The general requirements for recordkeeping under part 211 (21 part 211) are set forth in § 211.180. Any production, control, or distribution record associated with a batch and required to be maintained in compliance with part 211 must be retained for at least 1 year after the expiration date of the batch and, for certain OTC drugs, 3 years after distribution of the batch (§ 211.180(a)). Records for all components, drug product containers, closures, and labeling are required to be maintained for at least 1 year after the expiration date and 3 years for certain OTC products (§ 211.180(b)).

All part 211 records must be readily available for authorized inspections during the retention period (§ 211.180(c)), and such records may be retained either as original records or as true copies (§ 211.180(d)). In addition, 21 CFR 11.2(a) provides that ''For records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.'' To the extent this electronic option is used, the burden of maintaining paper records should be substantially reduced as should any review of such records.

In order to facilitate improvements and corrective actions, records must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures (§ 211.180(e)). Written procedures for these evaluations are to be established and include provisions for a review of a representative number of batches and, where applicable, records associated with the batch, and provisions for a review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.

Written procedures, referred to here as standard operating procedures (SOP's), are required for many part 211 records. The current SOP requirements were initially provided in a final rule published in the **Federal Register** of September 29, 1978 (43 FR 45014), and are now an integral and familiar part of the drug manufacturing process. The major paperwork impact of SOP's results from their creation. Thereafter, SOP's need to be periodically updated. A combined estimate is provided in