

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, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1471.

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:

Title: Electronic Records; Electronic Signatures—21 CFR Part 11

Description: FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records in place of paper records. The regulations will become effective on August 20, 1997. Under these regulations, records and reports may be submitted to FDA electronically, provided the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures. The reporting provision (§ 11.100) requires

persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

Description of Respondents: Businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

Most of the burden created by the information collection provisions of this final rule will be a one-time burden associated with the creation of standard operating procedures, validation, and certification. The agency anticipates that the use of electronic media will result in a substantial net reduction in the paperwork burden associated with maintaining FDA-required records.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Frequency per Recordkeeper	Hours per Recordkeeper	Total Hours
11.10	50	40	2,000
11.30	50	40	2,000
11.50	50	40	2,000
11.300	50	40	2,000
Total Recordkeeping Burden Hours			8,000

There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Hours per Response
11.100	1,000	1	1,000
Total Reporting Burden Hours			1,000

There are no capital costs or operating and maintenance costs associated with this information collection.

Dated: June 16, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 97-16178 Filed 6-19-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F-0170]

Toyo-Morton, Ltd.; Filing of Food Additive Petition; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a

notice that appeared in the **Federal Register** of April 30, 1997 (62 FR 23467). The document announced that Toyo-Morton, Ltd., filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyester-epoxy-urethane adhesive for use as a nonfood contact layer of laminated articles intended for use in contact with food. The document published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lajuana D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

In FR Doc. 97-11078, appearing on page 23467 in the **Federal Register** of Wednesday, April 30, 1997, the following correction is made:

1. On page 23467, in the third column, Docket No. "97C-0171" is corrected to read "97F-0170".

Dated: June 9, 1997.

Alan M. Rulis,
Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.
[FR Doc. 97-16236 Filed 6-19-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.