estimates the total annual number of respondents submitting requests for fast track designation to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) will be approximately 45. To obtain this estimate, FDA averaged the number of requests for fast track designation received by CBER and CDER in the 3-year period of 1998 to 2000. For these 3 years, CBER and CDER together received a yearly average of 53 requests from 45 respondents. The rate of submissions is not expected to change significantly in the next few years. FDA estimates that the number of hours needed to prepare a request for fast track designation may range between 40 and 80 hours per request, depending on the complexity of each request, with an average of 60 hours per request, as indicated in table 1 of this document.

Not all requests for fast track designation may meet the statutory standard. Of the average 53 requests made per year, the agency granted 33 requests for fast track designation. For each of the 33 granted requests, FDA estimates that a premeeting package was submitted to the agency. FDA estimates that a premeeting package needs more preparation time than needed for a designation request because the issues may be more complex and the data may need to be more developed. FDA estimates that the preparation hours may generally range between 80 and 120 hours, with an average of 100 hours per package, as indicated in table 1 of this document.

The hour burden estimates contained in table 1 of this document are for information collections requests in the guidance only and do not include burden estimates for statutory requirements specifically mandated by the act, the PHS Act, or implementing regulations. FDA estimates the burden of this collection of information as follows:

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation request	45	1.18	53	60	3,180
Premeeting packages	33	1.00	33	100	3,300
Total					6,480

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

Dated: October 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–26575 Filed 10–22–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0178]

Agency Information Collection Activities; Announcement of OMB Approval; Premarket Notification 510(k) Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Premarket Notification 510(k) Submissions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 18, 2001 (66 FR 37479), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0120. The approval expires on September 30, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: October 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–26573 Filed 10–22–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0276]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods With Vinclozolin Residues

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.

DATES: Submit written comments on the collection of information by November 23, 2001.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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

Suggested Documentation for Demonstrating Compliance With the Channels of Trade Provision for Foods With Vinclozolin Residues Description

Under the pesticide tolerance reassessment process that the Environmental Protection Agency (EPA) was mandated to carry out under the Food Quality Protection Act of 1996 (FQPA), EPA has proposed to revoke the