multiple claims and other labeling statements on food packages may affect how consumers perceive a product or a label, which may in turn affect their dietary choices. Results of the study will not be used to develop population estimates.

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take 1 hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,600 invitations, each taking 2 minutes (0.033 hour), will need to be sent to panelists to have 200 of them complete a 15-minute (0.25 hour) pretest. The total for the pretest activities is 106 hours (53 hours + 50 hours). For the survey, we estimate that 32,000 invitations, each taking 2 minutes (0.033 hour) to complete, will need to be sent to the consumer panel to have 3,000 of its members complete a 15-minute (0.25 hour) questionnaire. The total for the survey activities is 2,056 hours (1,056 hours + 1,000 hours). Thus, the total estimated burden is 2,174 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Cognitive interview screener	72	1	72	5/60	6
Cognitive interview	9	1	9	1	9
Pretest invitation	1,600	1	1,600	2/60	53
Pretest	200	1	200	15/60	50
Survey invitation	32,000	1	32,000	2/60	1,056
Survey	4,000	1	4,000	15/60	1,000
Total					2,174

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

II. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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9. Drichoutis, A.C., Lazaridis, P. and Nayga, R.M., "Consumers' Use of Nutritional Labels: a Review of Research Studies and Issues," *Academy of Marketing Science Review,* 2006(9), 2006. Available at *http://www.amsreview.org/articles/drichoutis09-2006.pdf.*
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12. Roe, B., Levy, A.S., and Derby, B.M., "The Impact of Health Claims on Consumer Search and Product Evaluation Outcomes: Evidence from FDA Experimental Data," *Journal of Public Policy and Marketing,* 18(1): 89–105, 1999.
13. LeGault, L., Brandt, M.B., McCabe, N., Adler, C., Brown, A.-M., and Brecher, S., "2000–2001 Food Label and Package Survey: An Update on Prevalence of Nutrition Labeling and Claims on Processed, Packaged Foods," *Journal of the American Dietetic Association,* 104(6): 952–8, 2004.

Dated: April 8, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8908 Filed 4–12–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0237]

Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the

Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements for a New Drug Application (NDA) holder to notify the Agency if an authorized generic drug is marketed by clearly including this information in an easily accessible place in the annual report and by sending a copy of the relevant portion of the annual report to a central contact point in the Agency.

DATES: Submit either electronic or written comments on the collection of information by June 13, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the OMB control number 0910–0646. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs—21 CFR 314.81(b)(2)—(OMB Control Number 0910–0646—Extension)

In the **Federal Register** of July 28, 2009 (74 FR 37163), FDA published a final rule that required the holder of an NDA to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act, which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

During the past several years, FDA has been reviewing annual reports it has received under § 314.81(b)(2) (21 CFR 314.81(b)(2)) to discern whether an authorized generic drug is being marketed by the NDA holder. Based on information learned from this review and based on the number of annual reports the Agency currently receives under § 314.81(b)(2), we estimate that we will receive approximately 400 annual reports containing the information required under § 314.81(b)(2)(ii)(*b*), for authorized generic drugs that were marketed during the time period covered by an annual report submitted after January 1, 1999. Based on the number of sponsors that currently submit annual reports, we estimate that approximately 60 sponsors will submit these 400 annual reports with authorized generics. As indicated in table 1 of this document, we are estimating that the same number of annual reports will be submitted each year from the same number of sponsors containing the information required under § 314.81(b)(2)(ii)(*b*), and that the same number of copies of that portion of each annual report containing the authorized generic drug information will be submitted from the same number of sponsors. Concerning the hours per response, based on our estimate of 40 hours to prepare each annual report currently submitted under § 314.81(b)(2), we estimate that sponsors will need approximately 1 hour to prepare the information required under § 314.81(b)(2)(ii)(*b*) for each authorized generic drug that was marketed during the time period covered by an annual report submitted after January 1, 1999; approximately 15 minutes to prepare the information required under § 314.81(b)(2)(ii)(*b*) for each subsequent annual report; and approximately 3 minutes to submit to FDA a copy of that portion of each annual report containing the authorized generic drug information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR 314.81(b)(2)(ii)(*b*)	Number of respondents	Number of reponses per respondent	Total annual respondents	Average burden per response (in hours)	Total hours
Authorized generic drug information on first marketed generics in an annual report under § 314.81(b)(2)(ii)(b) ..	60	6.7	400	1	400
Authorized generic drug information submitted in each subsequent annual report	60	6.7	400	15/60	100

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR 314.81(b)(2)(ii)(*b*)	Number of respondents	Number of reponses per respondent	Total annual respondents	Average burden per response (in hours)	Total hours
The submission of a copy of that portion of each annual report containing authorized generic drug information	60	6.7	400	3/60	20
Total	.....	.....	.....	.....	520

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

Dated: April 7, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8820 Filed 4–12–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0157]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed collection of information concerning requests by sponsors of investigational new drugs and applicants for new drug approvals or biologics licenses for fast track designation as provided in the guidance for industry on fast track drug development programs.

DATES: Submit either electronic or written comments on the collection of information by June 13, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review—(OMB Control Number 0910–0389)—Extension

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 506 (21 U.S.C. 356). The section authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to address an unmet medical need. Under section 112(b) of FDAMA, FDA issued guidance to industry on fast track policies and procedures outlined in section 506 of the FD&C Act. The guidance discusses collections of information that are specified under section 506 of the FD&C Act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving collection of information: (1) Fast track designation requests; (2) premeeting packages; and (3) requests to submit portions of an application. Of these, fast track designation requests and premeeting packages, in support of receiving a fast track program benefit, provide for additional collections of information not covered elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the Agency, may, in some cases, be incorporated into the request by referring to the information rather than resubmitting it.

Under section 506(a)(1) of the FD&C Act, an applicant who seeks fast track designation is required to submit a request to the Agency showing that the product: (1) Is intended for a serious or life-threatening condition and (2) has the potential to address an unmet