disease, disability, and death. The NTCP's four goal areas are: (1) The prevention of initiation of tobacco use among young people, (2) the elimination of nonsmokers' exposure to secondhand smoke, (3) the promotion of quitting among adults and young people, and (4) the elimination of tobacco-related disparities.

CDC proposes to conduct the National Adult Tobacco Survey (NATS) in order to collect essential information on key indicators of the effectiveness for the NTCP. The NATS will be a one-time, stratified, random-digit dialed telephone survey of non-institutionalized adults 18 years of age and older. In order to yield results that are representative and comparable at both national and state levels, information will be collected from 3,000 respondents per state and the District of Columbia. In addition, a total of approximately 3,000 interviews will be conducted specifically from a national sample of cell phone users in an attempt to include the growing population of households that exclusively use cell phones and would be missed in a survey relying only on land-lines.

Information collected through the NATS will be used to: (1) Generate state-level estimates of tobacco use for males and females, (2) generate state-level estimates of tobacco use for minority groups comprising a major component of a given state's population, (3) develop estimates of tobacco use at the national level by gender and race/ethnicity, and (4) support the evaluation of comprehensive state-based Tobacco Control Programs using key outcome indicators at the state and national levels. Study results will have significant implications for the development of policies and programs aimed at preventing or reducing tobacco use. There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Adults ages 18 or older	National Adult Tobacco Survey	156,000	1	22/60	57,200

Dated: June 1, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–13301 Filed 6–5–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0251]

Agency Information Collection Activities; Proposed Collection; Comment Request; User Fee Cover Sheet; Form FDA 3397

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 Form FDA 3397, User Fee Cover Sheet, that must be submitted along with certain drug and biologic product applications and supplements.

DATES: Submit written or electronic comments on the collection of information by August 7, 2009.

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: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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 comment 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.

User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910–0297)—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379g and 379h), the Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102–571), as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188), and most recently by the Food and Drug Administration

Amendments Act of 2007 (Public Law 110–85), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications, or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. Form FDA 3397, the user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2008, there are an estimated 255 manufacturers of products subject to the user fee provisions of PDUFA. However, not all manufacturers will have any submissions, and some may have multiple submissions in a given year. The total number of annual responses is based on the number of submissions received by FDA in FY 2008. CDER received 3,107 annual responses that include the following submissions: 147 new drug applications; 13 biologics license applications; 1,813 manufacturing supplements; 987 labeling supplements; and 147 efficacy supplements. CBER received 810 annual responses that include the following submissions: 9 biologics license applications; 743 manufacturing supplements; 48 labeling supplements; and 10 efficacy supplements. Based on the previous submissions that were received, the rate of these submissions is not expected to change significantly in the next few years. The estimated hours per response are based on past FDA experience with the various submissions, and the average is 30 minutes.

FDA is revising Form FDA 3397 in the following ways: (1) By including an additional question regarding redemption of a priority review voucher; (2) by deleting the exclusion for certain applications submitted under section 505(b)(2) of the FD&C Act (21 U.S.C. 355(b)(2)); and (3) by making several minor editorial changes.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	255	15.36	3,917	0.5	1,959

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

Dated: June 1, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–13276 Filed 6–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369] (formerly Docket No. 2007D–0169)

Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of May 31, 2007, FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' explaining the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of final product-specific BE recommendations.

DATES: Submit written or electronic comments on the draft and revised draft product-specific BE recommendations listed in this notice by September 8, 2009.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft product-specific BE recommendations 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the recommendations.

FOR FURTHER INFORMATION CONTACT: Doan T. Nguyen, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9314.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 31, 2007 (72 FR 30388), FDA announced the availability of a draft guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/cder/guidance/bioequivalence/default.htm*. As described in that draft guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for