152) (collectively, the ''Affordable Care Act''), ''Preservation of Resident Cap Positions from Closed Hospitals.'' Specifically, section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency cap slots after a hospital that trained residents in an approved medical residency program(s) closes. St. Vincent's Medical Center's official date of termination of the Medicare provider agreement and date of closure is October 31, 2010. The published notice, announcing the hospital closure and initiating the application process to preserve St. Vincent's resident cap positions stated that the application deadline was September 28, 2011. The date of September 28, 2011, was chosen since the procedure described in the November 24, 2010 **Federal Register** (75 FR 72215) for initiating an application process specifies that the application deadline would be 4 months after issuance of the notice to the public (that is, September 28, 2011, is 4 months after May 31, 2011).

Specifically, section 5506 of the Affordable Care Act instructs the Secretary to increase the FTE resident caps for other hospitals based upon the FTE resident positions in teaching hospitals that closed ''on or after a date that is 2 years before the date of enactment'' (that is, March 23, 2008). In the November 24, 2010 **Federal Register** (75 FR 72215), we stated that hospitals wishing to apply for FTE resident cap slots from teaching hospitals that closed between March 23, 2008 and through and including August 3, 2010, must submit applications to CMS by April 1, 2011. We further stated that for any teaching hospital closures occurring after August 3, 2010, separate notice would be made announcing the closure and initiating an application process for those slots and a future application deadline. The first application process with the application deadline of April 1, 2011, spanned over a 2-year timeframe (covering all hospital closures between March 28, 2008 and through and including August 3, 2010), and involved 15 closed teaching hospitals, generating a very large number of applications and slots to be redistributed. The closure of St. Vincent's Medical Center occurred on October 31, 2010, and the notice announcing the closure and initiating the application process was published on May 31, 2011, establishing the September 28, 2011 application deadline. Thus, the application period CMS initiated for the preservation of FTE resident slots due to the closure of St. Vincent's Medical Center overlaps with the period during which CMS is processing and reviewing the applications received under the first expansive section 5506 application process, and issuing final determinations to hospitals that may receive increases to their FTE resident caps. Moreover, we note that St. Vincent's Medical Center is located in the same CBSA as 3 (of the 15) hospitals that closed between March 23, 2008 through August 3, 2010, and many of the hospitals wishing to apply for slots from St. Vincent's Medical Center have indicated that it would be helpful to receive the results of their applications submitted under the first section 5506 process in order to make informed decisions regarding the number of slots for which to apply from St. Vincent's Medical Center under this separate application process. CMS does not have a specific deadline by which to issue final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act under the initial expansive application process, yet we understand the concerns of these hospitals and believe it is appropriate, in this case, to extend the application deadline for FTE resident slots from St. Vincent's Medical Center. Accordingly, we are extending the application deadline for FTE resident slots from St. Vincent's Medical Center from September 28, 2011 to December 1, 2011. We will consider applications received no later than 5 p.m. (e.s.t) December 1, 2011. Applications must be received, not postmarked, by this date.

We continue to refer readers to *http://www.cms.gov/AcuteInpatientPPS/06_dgme.asp#TopOfPage* to download a copy of the CMS Evaluation Form 5506, which is the application form that hospitals are to use to apply for slots under section 5506 of the Affordable Care Act. In addition, readers can access this Web site for a copy of the CY 2011 OPPS November 24, 2010 final rule, for an explanation of the policy and procedures for applying for slots and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Social Security Act, as provided by section 5506 of the Affordable Care Act. The mailing addresses for the CMS New York Regional Office and the CMS Central Office are included in this application form.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 1, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–23120 Filed 9–8–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0624]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notice of Participation

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 reporting requirements for filing a notice of participation with FDA.

DATES: Submit either electronic or written comments on the collection of information by November 8, 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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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.

Notice of Participation—21 CFR 12.45 (OMB Control Number 0910–0191)—Extension

Section 12.45 (21 CFR 12.45), issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in 21 CFR 12.85, or, in the case of a hearing before a Public Board of Inquiry, concerning disclosure of data and information by participants (21 CFR 13.25). In accordance with § 12.45(e), the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the prehearing conference and commits participation.

The respondents are individuals or households, State or local governments, not-for-profit institutions and businesses, or other for-profit groups and institutions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
12.45	4	1	4	3	12

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

The burden estimates for this collection of information are based on Agency records and experience over the past 3 years.

Dated: September 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23105 Filed 9–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0608]

Agency Information Collection Activities; Proposed Collection; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

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 revisions to Form FDA 3500 and Form FDA 3500A, and proposed consumer version of Form FDA 3500 (known as the MedWatch reporting form) used in the FDA Medical Products Reporting Program.

DATES: Submit either electronic or written comments on the collection of information by November 8, 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: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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