

with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, Bacillus anthracis, although there is no current domestic emergency involving anthrax, no current heightened risk of an anthrax attack, and no credible information indicating an imminent threat of an attack involving Bacillus anthracis. Pursuant to section 564(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3(b), and on the basis of such determination, on October 1, 2008, former Secretary of Health and Human Services, Michael O. Leavitt, declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a).¹ Pursuant to section 564(b)(2)(B) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3(b), and on the basis of Secretary Chertoff's September 23, 2008 determination, I hereby renew former Secretary Leavitt's October 1, 2008 declaration of an emergency, which I

previously renewed on October 1, 2009, justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). I am issuing this notice in accordance with section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(4).

Dated: September 24, 2010.
Kathleen Sebelius,
Secretary.
[FR Doc. 2010-24840 Filed 9-30-10; 11:15 am]
BILLING CODE 4150-37-P

OMB No.: 0970-0175.

Description: Section 466(a)(5)(C) of the Social Security Act requires States to pass laws ensuring a simple civil process for voluntarily acknowledging paternity under which the State must provide that the mother and putative father must be given notice, orally and in writing, of the benefits and legal responsibilities and consequences of acknowledging paternity. The information is to be used by hospitals, birth record agencies, and other entities participating in the voluntary paternity establishment program that collect information from the parents of children that are born out of wedlock.

Respondents: The parents of children that are born out of wedlock.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Voluntary Establishment of Paternity—NPRM.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
None	1,167,097	1	0.17	198,406.49
Estimated Total Annual Burden Hours:				198,406.49

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 30, 2010.
Robert Sargis,
Reports Clearance Officer.
[FR Doc. 2010-24893 Filed 10-4-10; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0502]

Agency Information Collection Activities; Proposed Collection; Comment Request; National Consumer Surveys on Understanding the Risks and Benefits of FDA-Regulated Medical Products

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 and to allow 60 days for

¹ Pursuant to section 564(b)(4) of the FFDCFA, notice of the determination by the Secretary, DHS,

and the declaration by the Secretary, HHS, was provided at 73 FR 58242 (October 6, 2008).

public comment in response to the notice. This notice solicits comments on the National Consumer Surveys on Understanding the Risks and Benefits of FDA-Regulated Medical Products.

DATES: Submit either electronic or written comments on the collection of information by December 6, 2010.

ADDRESSES: Submit either electronic or written 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., P150-400B Rockville, MD 20850, 301-796-3794,

JonnaLynn.Capezzuto@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 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.

National Consumer Surveys on Understanding the Risks and Benefits of FDA-Regulated Medical Products

Risks and benefits are inherent in all FDA-regulated medical products, including drugs, biologics, and medical devices (e.g., pacemakers, implantable cardiac defibrillators, contact lenses, infusion pumps). FDA plays a critical oversight role in managing and preventing injuries and deaths related to medical product use. However, the users of FDA-regulated products are ultimately the ones who determine which products are used and how they are potentially misused. For this reason, it is critical that the public understand the risks and benefits of FDA-regulated medical products to a degree that allows them to make rational decisions about product use.

FDA's responsibility includes communicating about medical products. This encompasses communications that FDA generates and those it oversees through regulation of product manufacturers' and distributors' communications. Activities include, but are not limited to, recall notices, warnings, public health advisories and notifications, press releases, and information made available on its Web site. FDA also regulates communications drafted and disseminated by manufacturers and distributors of many medical products, including all the communications (advertising and labeling) about prescription drugs, biologics, and restricted medical devices, and a subset of communications (omitting advertising) about nonprescription drugs and other medical devices. In order to conduct educational and public information programs relating to these responsibilities, as authorized by Section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. section 393), it is beneficial for FDA to conduct research and studies relating to health information as authorized by

section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)).

In conducting such research, FDA will employ nationally representative surveys of consumers to assess whether the information being disseminated by both the agency and the entities it regulates is appropriately reaching targeted audiences in an understandable fashion. Specifically, the surveys will assess public understanding about the benefits and risks of medical products and FDA's role in regulating these products. The surveys will assess behaviors and beliefs related to the use of medical products, when consumers desire emerging risk information, the likelihood of reporting serious side effects that might be associated with medical product use, perceptions of the credibility of FDA and other potential sources of risk and benefit information, and satisfaction with FDA's communications-related performance.

Parallel surveys of 1,500 non-institutionalized U.S. adults will be administered. One survey of 1,500 subjects will be a telephone survey, and the second survey of another 1,500 subjects will be conducted with members from an Internet panel. Both survey samples will be constructed to be representative of the U.S. population, and both will take approximately 15 minutes to administer. Results from each survey will be compared to provide insight into the best methodology for future studies.

The information collected will be used by FDA in the development of more effective risk communication strategies and messages. The surveys will provide FDA insight as to how well the public understands and incorporates risk/benefit information into their belief structures, and how well the public understands the context within which FDA makes decisions on medical product recalls and warnings. Using this information, the agency will more effectively design messages and select formats and distribution channels that have the greatest potential to influence the target audience's attitudes and behavior in a favorable way. Frequency of *Response*: On occasion. *Affected Public*: Individuals or households; *Type of Respondents*: Members of the public.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Type of Response	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretests	30	1	30	0.25	8

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Type of Response	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screeners	6,700	1	6,700	0.10	670
Telephone survey	1,500	1	1,500	0.25	375
Internet panel survey	1,500	1	1,500	0.25	375
Total					1,428

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

These estimates are based on FDA's and the contractor's experience with previous surveys. Prior to administering the surveys with the entire sample, FDA plans to conduct pretests with up to 30 adults; these are meant to evaluate the effectiveness of the programming of the interview protocol, online filters, and skip patterns.

Dated: September 30, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0464]

Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications on Biological Products

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on communication studies involving biological products, including vaccines and blood products, that are regulated by FDA. This information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the Agency's mission to protect the public health.

DATES: Submit either electronic or written comments on the collection of information by December 6, 2010.

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 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.

Testing Communications on Biological Products—New

FDA is authorized by Section 1003(d)(2)(D) of the Federal Food Drug and Cosmetic Act (21 U.S.C. Section 393(d)(2)(D)) (Attachment 2) to conduct educational and public information programs relating to the safety of regulated biological products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. FDA expects that improving communications about biological products including vaccines and blood products will involve many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about biological product use. Knowledge of consumer and healthcare professional decision-making processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using biological products including vaccines and blood products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with