

screened and selected from Individuals and Households, Businesses, Organizations, and/or State, Local or

Tribal Government. There is no cost to respondents other than their time. The

estimated total burden hours for this data collection activity are 268.

Type of collection	Average number of respondents per activity	Annual frequency per response	Average number of activities	Average hours per response
Online surveys, Telephone Surveys, Focus Groups, In person observation/testing .....	67	1	5	48/60

**Leroy A. Richardson,**  
Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Centers for Disease Control and  
Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Department of Health and Human Services, has been renewed for a 2-year period through May 21, 2016.

For information, contact William Cibulas, Ph.D., Designated Federal Officer, Board of Scientific Counselors, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Department of Health and Human Services, 4770 Buford Highway, Mailstop F61, Chamblee, Georgia 30341, telephone (770) 488-0662 or fax (770) 488-3385.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Elaine L. Baker,**  
Director, Management Analysis and Services  
Office, Centers for Disease Control and  
Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0129]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications

**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 information collection in an application for a proposed biosimilar product and an application for a supplement for a proposed interchangeable product.

**DATES:** Submit either electronic or written comments on the collection of information by April 6, 2015.

**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:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

#### General Licensing Provisions; Section 351(k) Biosimilar Applications (OMB Control Number 0910-0719)—Extension

The Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111-148) contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which amends the Public Health Service Act (PHS Act) and establishes an abbreviated licensure pathway for