VI. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). Since this notice revises the process we will use to make an NCD for a specific item or service and has no economic impact on the Medicare program, we have determined this is not a major notice.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 to $25 million or less annually. We have determined that this notice will not have a significant economic impact on a substantial number of small entities. We believe that few small entities will submit requests. We estimate that approximately five beneficiaries or small entities may submit a request in a year.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We have determined that this notice will not have a consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State, local, or tribal governments, preempts State law, or otherwise has Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Sections 1862, 1869(f), and 1871 of the Social Security Act (42 U.S.C. 1395y, 1395ff(b)(3), and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare-Hospital Insurance; and Program No. 93774, Medicare-Supplementary Medical Insurance Program).

Dated: September 15, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 15, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–24361 Filed 9–25–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Counter Terrorism Products Regulated by the Center for Biologics Evaluation and Research: Effective Strategies to Assist in Product Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Counter Terrorism Products Regulated by the Center for Biologics Evaluation and Research: Effective Strategies to Assist in Product Development.'' The purpose of the public workshop is to provide a forum for discussing strategies to assist in the effective development of products regulated by the Center for Biologics Evaluation and Research (CBER) that may be used in counter terrorism efforts (e.g., vaccines, blood and blood products including immunoglobulins, gene therapies, and human cellular and tissue-based products).

Date and Time: The workshop will be held on October 23, 2003, from 8:30 a.m. to 5 p.m., and on October 24, 2003, from 8:30 a.m. to 5 p.m.

Location: The workshop will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD.

Contact Person: Gloria Blankenship, CBER (HFM–49), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–2000, FAX 301–827–3079, e-mail: *Blankenship@cber.fda.gov*.

Registration: Mail, e-mail, or fax your registration information (including name, professional degree, title, e-mail address, firm name, address, telephone, and fax number) to Gloria Blankenship, (see *Contact Person*) by October 10, 2003. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Gloria Blankenship (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The purpose of this public workshop is to provide a forum for sharing information and strategies to assist in the efficient and successful development of products regulated by CBER and used for counter terrorism efforts. CBER is interested in promoting a discussion of issues related to the development of counter terrorism products, including manufacturing and clinical issues, and other relevant issues. The workshop is intended to help sponsors address commonly asked questions and avoid common misunderstandings and to provide practical information on successful product development strategies.

FDA invites participants to submit issues for discussion prior to the workshop. There will be an opportunity to raise additional questions and issues for discussion at the meeting. Mail or fax your issues and questions to Gloria Blankenship (see *Contact Person*) by October 10, 2003.

FDA will post on CBER's Web site (*http://www.fda.gov/cber/*) the agenda for this meeting, when finalized.

Transcripts: Please note that transcripts of the meeting will not be prepared.

Dated: September 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–24303 Filed 9–25–03; 8:45 am]

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