and safety effects; distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economic effects of $100 million or more annually. We have determined this to be a major rule. It provides $400 million to a specialized category of low-income Medicare beneficiaries.

The RFA requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, States and individuals are not considered to be small entities.

This proposed notice would allocate, among the States, Federal funds to provide Medicaid payment for Medicare Part B premiums for QIs. The total amount of Federal funds available during a Federal fiscal year and the formula for determining individual State allotments are specified in the law. Because the formula for determination of State allotments is specified in the statute, there were no other options to be considered. Therefore, we have applied the statutory formula for the State allotments except for the use of specified data. Because the data specified in the law were not available, we have used comparable data from the U.S. Census Bureau on the number of possible QIs in the States, as described in detail in the January 26, 1998 **Federal Register**. Since the statutory formula calls for an estimate of individuals who could qualify for QI status rather than the number of individuals who actually have that status, the exact numbers of those individuals will always be uncertain. These new allotments for FY 2002 incorporate the latest data from the U.S. Census Bureau from 1999 to 2001, as specified in the footnotes to the preceding table.

We believe the statutory provisions that would be implemented in this proposed notice would have a positive effect on States and individuals. Federal funding at the 100 percent matching rate is available for Medicare cost-sharing for Medicare Part B premium payments for selected QIs, and a greater number of low-income Medicare beneficiaries would be eligible to have their Medicare Part B premiums paid under Medicaid.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 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 a Metropolitan Statistical Area and has fewer than 100 beds.

We are not preparing analyses for either the RFA or section 1102(b) of the Act, because we have determined and certify that this proposed notice would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, also requires that agencies assess anticipated costs and benefits before issuing any proposed rule and a final rule preceded by a proposed rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or any the private sector, or $110 million or more. This notice would have no consequential effect on the governments mentioned or on the private sector.

We have reviewed this notice under the threshold criteria of Executive Order 13132, Federalism. Because this proposed notice would simply provide notice of funding ceilings, as determined under the statute, we have determined that this proposed notice would not significantly affect the rights, roles, and responsibilities of States.

In accordance with the provisions of Executive Order 12866, this proposed notice with comment period was reviewed by the Office of Management and Budget (OMB).

**Authority:** Sections 1902(a)(10)(E) and 1933 of the Social Security Act (42 U.S.C. 1396a(a)(10)(E) and 1396x).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: April 28, 2002.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: August 26, 2002.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 02–22228 Filed 8–29–02; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0102]**

### Agency Information Collection Activities; Announcement of OMB Approval; Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 28, 2002 (67 43633), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0374. The approval expires on August 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: August 23, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–22115 Filed 8–29–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0159]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Focus Groups as Used by the Food and Drug Administration

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by September 30, 2002.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Mark L. Pincus, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Focus Groups as Used by the Food and Drug Administration—New Collection**

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such, compliments other important research findings to develop these proposals. Focus groups do provide an important role in gathering information because they allow for a more in-depth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies.

Also, information from these focus groups will be used to develop policy and redirect resources, when necessary, to our constituents. If this information is not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

In the **Federal Register** of May 24, 2002 (67 FR 36613), the agency requested comments on the proposed collection of information. FDA received four comments, but they did not pertain to the information collection though one heartily supported the use of focus groups as an instrument to help FDA better understand how well respondents comprehend health issues.

FDA estimates the burden for completing the forms for this collection of information as follows:

The total annual estimated burden imposed by this collection of information is 2,884 hours annually.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Center | Subject | No. of Focus Groups per Study | No. of Focus Group Sessions Conducted Annually | Number of Participants per Group | Hours of Duration for Each Group (includes screening) | Total Hours |
|---|---|---|---|---|---|---|
| Center for Biologics Evaluation and Research. | May use focus groups when appropriate. | 1 | 5 | 9 | 1.58 | 71 |
| Center for Drug Evaluation and Research. | Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication). | 10 | 100 | 9 | 1.58 | 1,422 |
| Center for Devices and Radiological Health. | Varies (e.g., FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves). | 5 | 25 | 9 | 2.08 | 468 |
| Center for Food Safety and Applied Nutrition. | Varies (e.g., food safety, nutrition, dietary supplements, and consumer education). | 8 | 32 | 9 | 1.58 | 455 |
| Center for Veterinary Medicine. | Varies (e.g., food safety, labeling, cosmetic safety and labeling). | 5 | 25 | 9 | 2.08 | 468 |
| Total | | 29 | 187 | | 1.99 | 3,352 |

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

Annually, FDA projects about 29 focus group studies using 187 focus groups lasting an average of 1.99 hours each. We have allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: August 26, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–22284 Filed 8–29–02; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Publication of OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries

**AGENCY:** Office of Inspector General (OIG), HHS.