DOJ has agreed to represent the employee, or

d. the United States Government is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court or adjudicatory body is compatible with the purpose for which the agency collected the records.

6. To assist a CMS contractor (including, but not necessarily limited to fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such program.

7. To assist another Federal agency or an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures.

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E) 65 FR 82462 (12–28–00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164–512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that an individual could, because of the small size, use this information to deduce the identity of the beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on computer diskette and magnetic media.

RETRIEVABILITY:

Information can be retrieved by the name, SSN, and/or HICN of claimant.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

CMS will transfer to and maintain in an archival file for a total period not to exceed 7 years. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Appeals Policy, Medicare Enrollment & Appeals Group, Center for Beneficiary Choices, CMS, Mail Stop C2–12–16, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, HICN, address, date of birth, and gender, and for verification purposes, the subject individual's name (woman's maiden name, if applicable), and SSN. Furnishing the SSN is voluntary, but it may make searching for a record easier and prevent delay.

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also specify the record contents being sought. (These procedures are in accordance with department regulation 45 CFR 5b.5(a)(2)).

CONTESTING RECORDS PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the records and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These Procedures are in accordance with Department regulation 45 CFR 5b.7).

RECORDS SOURCE CATEGORIES:

Sources on information contained in this records system is obtained from the reconsideration requests made by or on behalf of Medicare beneficiaries and from inquiries from congressional offices, health plans, providers, state insurance commissioners, state regulators, disenrollment surveys, Medicare carriers or intermediaries, and QIO records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E6–16852 Filed 10–11–06; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0130]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Trans Fatty Acids in Nutrition Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by November 13, 2006.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Food Labeling; Trans Fatty Acids in Nutrition Labeling—21 CFR 101.9(C)(2)(ii) and 101.36(b)(2) (OMB Control Number 0910–0515)—Extension

Section 403(q) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)) establishes the requirements for nutrition labeling of foods. In particular, section 403(q)(1)(A) and 403(q)(1)(B) require that the label or labeling of a food bear nutrition information on the amount of nutrients present in a product. Section 403(q)(2) of the act permits FDA to require information about nutrients not specified in section 403(q)(1) if that additional information will assist consumers in maintaining healthy dietary practices. Section 403(q)(5)(F) of the act specifies the nutrition information that must be on the label or labeling of dietary supplements. Under these provisions of the act, FDA issued regulations in § 101.9(c)(2) (21 CFR 101.9(c)(2)) that require information on the amounts of fat and certain fatty acids in food products to be disclosed in the Nutrition Facts panel. Similarly, FDA issued regulations in § 101.36(b) (21 CFR 101.36(b)) that specify the nutrition information that must be on the label or labeling of dietary supplements. In particular, §§ 101.9(c)(2)(ii) and 101.36(b)(2) require that the amount of trans fatty acids present in a food, including dietary supplements, must be declared on the nutrition label of conventional foods, and for dietary supplements, on a separate line immediately under the line for the declaration of saturated fat.

Respondents are expected to be persons and businesses, including small businesses.

In the **Federal Register** of April 11, 2006 (71 FR 18338), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received but unrelated to the information collection.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours	Total Operating Costs
101.9(c)(2)(ii)	10,490	27	278,100	2	556,200	$155,200
101.36(b)(2)	910	32	29,500	2	59,000	$16,500
Total					615,200	$171,700

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

FDA believes that the burden associated with the disclosure of trans fatty acid information on labels or in labeling food and dietary supplement products is largely a one-time burden created by the need for firms to revise the labels for those existing products that contain trans fatty acids.

FDA estimated that there were approximately 10,490 firms producing food products and 910 firms producing dietary supplement products that, because they contain trans fatty acids, were affected by §§ 101.9 and 101.36. The agency estimated that these firms needed to revise approximately 278,100 food labels and 29,500 dietary supplement labels, although only about 25 percent of these label changes would have to be made earlier than the firms planned. Because these firms were already disclosing information on total fat, saturated fat, and other significant nutrients on their product labels, based upon its knowledge of food and dietary supplement labeling, FDA estimated that firms would require less than 2 hours per product to comply with the nutrition labeling requirements of §§ 101.9 and 101.36.

Multiplying the total number of responses by the hours per response gives the total hours. FDA estimated operating costs by combining testing and relabeling costs ($44.9 million + $126.8 million). This total was then apportioned between §§ 101.9 and 101.36 according to the proportion of responses for each section. Based on the labeling cost model, FDA expected that, with a compliance period of over 2 years, 75 percent of firms will coordinate labeling revisions required by the trans fat final rule with other planned labeling changes for their products.

Dated: October 5, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0777] (formerly Docket No. 98D–0777)

Guidance for Industry on Investigating Out-of-Specification Test Results for Pharmaceutical Production; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production.'' This guidance provides information for the pharmaceutical industry on how to evaluate laboratory test results that fall outside of specification limits. The guidance is intended to provide clear and consistent communication of