Dated: August 19, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

CENTER FOR MEDICARE & MEDICAID SERVICES

Computer Match No. 2001–03

NAME:

Medicare Secondary Payer Program.

SECURITY CLASSIFICATION:

Level Three Privacy Act Sensitive.

PARTICIPATING AGENCIES:

Internal Revenue Service (IRS), Social Security Administration (SSA) and Centers for Medicare & Medicaid Services (CMS).

AUTHORITY FOR CONDUCTING MATCHING PROGRAM:

This agreement implements the provisions of section 1862(b)(5) of the Social Security Act, (42 U.S.C. 1395y(b)(5)), section 6103(l)(12) of the Internal Revenue Code, (26 U.S.C 6103(1)(12)), and the Privacy Act, (5 U.S.C. 552a) as amended.

PURPOSE(S) OF THE MATCHING PROGRAM:

1. The purpose of this agreement is to establish the conditions under which:

a. The Internal Revenue Service (IRS) agrees to disclose return information relating to taxpayer identity to the Social Security Administration (SSA); and

b. The SSA agrees to disclose return information relating to employer identity, commingled with taxpayer identity information disclosed by the IRS, to the Centers for Medicare & Medicaid Services (CMS).

2. These disclosures will provide CMS with information for use in determining the extent to which any Medicare beneficiary is covered under any Group Health Plan (GHP). This Matching Agreement between the Department of the Treasury Internal Revenue Service (IRS), and the Social Security Administration (SSA) and the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) is executed pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), as amended and the Office of Management and the Budget (OMB) Final Guidance interpreting that Act. This agreement implements the information matching provisions of 26 U.S.C. 6103(1)(12) and 42 U.S.C. 1395y(b)(5).

CATEGORIES OF RECORDS AND INDIVIDUALS COVERED BY THE MATCH:

IRS—IRS will disclose taxpayer identity information from the Individual Master File (IMF), Treas/IRS 24.030, published at 63 FR 69854 (12/17/ 98). The IRS component responsible for the disclosure of the return information is the Office of Government Liaison and Disclosure. **SSA**—SSA will extract identifying information of Medicare beneficiaries from the Master Beneficiary Record (MBR), SSA/OSR 09–60–0090, published at 65 FR 46997 (08/01/00). SSA will validate the taxpayer SSN by matching information from the IMF against the Master Files of Social Security Number Holders, (NUMIDENT), SSA/OSR 09–60–0058, published at 63 FR 14165 (03/24/98). SSA will extract employer identity information from the Earnings Recording and Self-Employment Income System, SSA/0SR 09–60–0059, referred to as the Master Earnings File (MEF), published at 62 FR 11939 (03/13/97). The SSA component responsible for the disclosure of the return information is the Office of Systems Requirements (OSR). **CMS**—CMS will utilize a database, System Number 09–70–4001, published at 57 FR 60818 (12/22/92), of the GHP information received from employers containing verified instances of employment and GHP coverage for Medicare beneficiaries and Medicare eligible spouses identified from the IMF and MEF extracts. CMS will match the GHP information against the Carrier Medicare Claims Records, System Number 09–70–0501, published at 59 FR 37243–02 (7/21/94), maintained at the CMS Common Working File (CWF), System Number 09–70–0526, published at 53 FR 52792 (12/29/88). CMS will match GHP information against the Carrier Medicare Claims Records, System Number 09–70–0501, published at 59 FR 37243–02 (7/21/94), maintained at the CMS Common Working File (CWF), System Number 09–70–0526, published at 53 FR 52792 (12/29/88), which is the repository database for current MSP information. This file contains information or records needed to properly process and pay medical insurance benefits to, or on behalf of, entitled beneficiaries who have submitted claims for Supplementary Medical Insurance Benefits (Medicare Part B). The file is accessed when a claim is submitted for payment. CMS will match GHP information against the Intermediary Claims Records, System Number 09–70–0503, published at 59 FR 37243–02 (7/21/94), maintained at the CWF.

This file contains information or records needed to properly process and pay Medicare benefits to, or on behalf of, eligible individuals. The file is accessed when a claim is submitted for payment. CMS will match GHP information against the National Claims History (NCH), which is contained in the National Claims History File, Privacy Act System, HHS, CMS, BDMS 09–70–0005 published at 59 FR 19181 (4/22/94), maintained at CMS Data Center (HDC), located in Baltimore, Maryland. NCH contains records needed to facilitate obtaining Medicare utilization review data that can be used to study the operation and effectiveness of the Medicare program. The CMS component responsible for receipt and verification of the return information is the Office of Information Services (CMS/OIS).

INCLUSIVE DATES OF THE MATCH:

The Matching Program shall become effective no sooner than 40 days after the report of the Matching Program is sent to OMB and Congress, or 30 days after publication in the **Federal Register**, which ever is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 04–20096 Filed 9–1–04; 8:45 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0320]

Guidance for Industry and Clinical Investigators on the Use of Clinical Holds Following Clinical Investigator Misconduct; 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 and clinical investigators entitled ''The Use of Clinical Holds Following Clinical Investigator Misconduct.'' This guidance provides information on FDA's use of its authority to impose a clinical hold on a study if FDA finds that a clinical investigator conducting the study has committed serious violations of our regulations pertaining to clinical trials involving human drug or biological products or has submitted false information to FDA or to the study's sponsor in any report. The guidance is intended to inform interested persons of the circumstances in which we may impose a clinical hold following the discovery of a clinical investigator's misconduct and the steps

we might take to protect human subjects from investigator misconduct.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rachel Behrman, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–594–6758; or Patricia Holobaugh, Center for Biologics Evaluation and Research (HFM–664), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6347.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and clinical investigators entitled ''The Use of Clinical Holds Following Clinical Investigator Misconduct.'' The guidance provides information on one use of our authority to impose a clinical hold on a study or a study site if FDA finds that human subjects are or would be exposed to an unreasonable and significant risk of illness or injury. The guidance describes the circumstances in which FDA may impose clinical hold based on credible evidence that a clinical investigator conducting the study has committed serious violations of our regulations pertaining to clinical trials involving human drug or biological products or has submitted false information to us or to the study's sponsor in any required report. The guidance is intended to inform interested persons of the circumstances in which we may impose a clinical hold following the discovery of a clinical investigator's misconduct and the steps we might take to protect human subjects from investigator misconduct.

In the **Federal Register** of August 27, 2002 (67 FR 55025), FDA announced the availability of a draft version of the guidance entitled ''The Use of Clinical Holds Following Clinical Investigator Misconduct.'' The August 2002 guidance gave interested persons an opportunity to submit comments through November 25, 2002. All comments received during the comment period have been carefully reviewed and, where appropriate, incorporated in the guidance. As a result of the public comments and editorial changes, the guidance is clearer than the draft version.

The guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance were approved under OMB control number 0910–0014.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the use of clinical holds to protect human subjects following clinical investigator misconduct in a clinical trial of a human drug or biological product. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. As with other guidance documents, we do not intend this document to be all-inclusive, and we caution that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cber/guidelines.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/oc/gcp/guidance.html*.

Dated: August 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–19983 Filed 9–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Customs and Border Protection

Modification of the National Customs Automation Program Test Regarding Reconciliation

AGENCY: Customs and Border Protection, Homeland Security.

ACTION: General notice.

SUMMARY: This document modifies the Customs and Border Protection Automated Commercial System (ACS) Reconciliation prototype test by: Adding to the kinds of issues that may be subject to Reconciliation post-entry importation claims arising under the United States-Chile Free Trade Agreement; requiring the use of compact disks (CDs) instead of floppy disks for submitting Reconciliation spreadsheets; requiring that the name identifying the spreadsheet on the CD be the Reconciliation entry number; and requiring use of .txt or .xls format for the spreadsheet. Other than these modifications, the test remains the same as set forth in previously published **Federal Register** notices. The document also announces the new addresses for the Reconciliation team (e-mail) and for Reconciliation submissions for the port of NY/Newark.

DATES: The test modifications set forth in this document are effective on October 4, 2004. The two-year testing period of this Reconciliation prototype commenced on October 1, 1998, and was extended indefinitely starting October 1, 2000. Applications to participate in the test will be accepted throughout the duration of the test.

ADDRESSES: Written inquiries regarding participation in the Reconciliation prototype test and/or applications to participate should be addressed to Mr. Richard Wallio, Reconciliation Team, Customs and Border Protection, 1300 Pennsylvania Ave., NW., Room 5.2A, Washington, DC 20229–0001. The e-mail address for inquiries regarding the