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

test is also available at *Recon.Help@dhs.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Wallio at (202) 344–2556.

SUPPLEMENTARY INFORMATION:

Background

Initially, it is noted that on November 25, 2002, the President signed the Homeland Security Act of 2002, 6 U.S.C. 101 *et seq.*, Pub. L. 107–296 (the HS Act), establishing the Department of Homeland Security and, under section 403(1) (6 U.S.C. 203(1)), transferring the U.S. Customs Service, including functions of the Secretary of the Treasury relating to the Customs Service, to the new department, effective on March 1, 2003. Most of the elements that comprised the U.S. Customs Service are now collectively known as U.S. Customs and Border Protection (CBP). The agency will be referred to by that name in this document, unless reference to the Customs Service (or Customs) is appropriate in a given context.

Reconciliation, a planned component of the National Customs Automation Program (NCAP), as provided for in Title VI (Subtitle B) of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182, 107 Stat. 2057 (December 8, 1993)), is currently being tested by CBP under the CBP Automated Commercial System (ACS) Prototype Test. Customs initially announced and explained the test in a general notice document published in the **Federal Register** (63 FR 6257) on February 6, 1998. Clarifications and operational changes were announced in six subsequent **Federal Register** notices: 63 FR 44303, published on August 18, 1998; 64 FR 39187, published on July 21, 1999; 64 FR 73121, published on December 29, 1999; 66 FR 14619, published on March 13, 2001, 67 FR 61200, published on September 27, 2002, and 67 FR 68238, published on November 8, 2002. A **Federal Register** (65 FR 55326) notice published on September 13, 2000, extended the prototype indefinitely. This document modifies the Reconciliation test by: (1) Expanding the issues subject to Reconciliation to include post-entry importation claims arising under the United States-Chile Free Trade Agreement; (2) requiring the use of compact disks (CDs) instead of floppy disks for submitting Reconciliation spreadsheets; (3) requiring that the name identifying the spreadsheet on the CD be the Reconciliation entry number; and (4) requiring use of .txt or .xls format for the spreadsheet. Aside from these modifications, the test remains as set forth in the previously published **Federal Register** notices.

The document also sets forth the new address for submitting Reconciliation entries for the port of NY/Newark and the new e-mail address for the Reconciliation team.

For application requirements, see the **Federal Register** notices published on February 6, 1998, and August 18, 1998. Additional information regarding the test can be found at *http://www.cbp.gov/xp/cgov/import/cargo_summary/reconciliation/*.

Reconciliation Generally

Reconciliation is the process that allows an importer, at the time an entry summary is filed, to identify undeterminable information (other than that affecting admissibility) to CBP and to provide that outstanding information at a later date. The importer identifies the outstanding information by means of an electronic ''flag'' which is placed on the entry summary at the time the entry summary is filed. The issues for which an entry summary may be ''flagged'' (for the purpose of later reconciliation) are limited and relate to: (1) Value issues; (2) classification issues, on a limited basis; (3) issues concerning value aspects of entries filed under heading 9802, Harmonized Tariff Schedule of the United States (HTSUS); (9802 issues); and (4) post-entry claims under 19 U.S.C. 1520(d) for the benefits of the North American Free Trade Agreement (NAFTA) for merchandise as to which such claims were not made at the time of entry.

The flagged entry summary (the underlying entry summary) is liquidated for all aspects of the entry except those issues that were flagged. The means of providing the outstanding information at a later date relative to the flagged issues is through the filing of a Reconciliation entry. The flagged issues will be liquidated at the time the Reconciliation entry is liquidated. Any adjustments in duties, taxes, and/or fees owed will be made at that time. (The Reconciliation test procedure for making post-entry NAFTA claims is explained in the February 6, 1998, and December 29, 1999, **Federal Register** notices.)

Test Modification

Use of Reconciliation To Make a Post-Entry US–CFTA Claim

On June 6, 2003, the United States and the Republic of Chile (Chile) entered into an agreement, the United States-Chile Free Trade Agreement (US–CFTA), which provides for, among other things, preferential tariff treatment (including duty free treatment) for goods that qualify as goods originating in the United States or Chile. The provisions of the US–CFTA were adopted by the United States with enactment of the United States—Chile Free Trade Agreement Implementation Act, Pub. L. 108–78, 117 Stat. 909 (19 U.S.C. 3805 note) (the Implementation Act).

Ordinarily, a claim for preferential tariff treatment under the US–CFTA is made at the time of entry, in accordance with the terms of the US–CFTA, the Implementation Act, and any applicable regulations. However, in some instances an importer is unable to make the claim at that time. In that instance, an importer can make a post-entry US–CFTA claim under 19 U.S.C. 1520(d) (section 1520(d)), pursuant to an amendment to that statute made by the Implementation Act. Under this amendment to section 1520(d), entries of goods qualifying under US–CFTA rules of origin were made eligible for liquidation or reliquidation when preferential tariff treatment under the US–CFTA was not claimed at the time of entry, notwithstanding that a protest under 19 U.S.C. 1514 (section 1514) was not filed. A claimant must file a claim under section 1520(d) within one year of the applicable importation and meet other requirements, such as documentary requirements. CBP has accepted post-entry 1520(d) US–CFTA claims before liquidation; these claims do not require reliquidation.

This notice announces that a post-entry 1520(d) claim for preferential tariff treatment under the US–CFTA also can be made under the Reconciliation test, in the same way as can a post-entry NAFTA claim. This alternative requires that an importer follow the Reconciliation test procedure which, in contrast to the ordinary section 1520(d) procedure described above, requires action at the time of entry. That action is to flag the entry summary for Reconciliation and later file a Reconciliation entry within one year of the applicable importation. As programming for US–CFTA Reconciliations is not yet complete, for the time being, a participant wishing to file a US–CFTA Reconciliation must follow the NAFTA Reconciliation process by flagging the entry summary for NAFTA. When programming is complete, participants will be notified with instructions on how to make a post-entry US–CFTA Reconciliation claim.

CBP emphasizes that once an importer flags an entry summary for US–CFTA issues (by, for the time being, actually flagging the entry summary for NAFTA), indicating that it is pursuing

the post-entry section 1520(d) claim through the Reconciliation process, the only means of perfecting the US–CFTA claim is by completing the Reconciliation process by filing a timely Reconciliation entry. (See the September 27, 2002, **Federal Register** notice for an explanation of this same limitation relative to NAFTA issues.) In this way, the flagging of an entry summary constitutes a commitment by the importer to perfect the US–CFTA 1520(d) claim through the Reconciliation process. Thus, once a Reconciliation program participant flags an entry summary to make a US–CFTA 1520(d) claim under the Reconciliation process, CBP will not accept a claim filed under the ordinary section 1520(d) procedure.

CBP notes that a NAFTA 1520(d) claim and a US–CFTA 1520(d) claim cannot be made together on the same Reconciliation entry. They must be filed as separate Reconciliation entries.

CBP recommends the use of the Reconciliation test for making post-entry US–CFTA claims because the test procedure provides the importer with several benefits. First, using the test procedure is a simpler means of filing claims: *i.e.*, the importer is able to make potentially thousands of US–CFTA claims on one Reconciliation entry. Second, the importer can receive one check from CBP rather than many (even up to thousands) upon CBP's liquidation of a Reconciliation entry and issuance of a refund. Third, because processing US–CFTA claims under Reconciliation is simpler for CBP, the refund delivery system is more efficient.

The test modification discussed above will be effective 30 days from the date this notice is published in the **Federal Register**. (The Reconciliation test procedure for making post-NAFTA claims is explained in the February 6, 1998, and the December 29, 1999, **Federal Register** notices.)

Other Changes

This notice also announces other changes to the Reconciliation test program procedure relative to submission of the Reconciliation spreadsheets. Because floppy disks are destroyed by X-ray and irradiation applications now used to screen government mail, participants must use CDs for submitting Reconciliation spreadsheets. CBP will upload the spreadsheet information on the CD to a secure Web site where it will be identified according to the Reconciliation entry number. Therefore, participants must save the spreadsheet on the CD according to the Reconciliation entry number in .txt or .xls format. Use of these formats is required to better protect the information from computer viruses. Finally, the CDs must be labeled as previously required (see the ACS *Reconciliation Prototype: A Guide to Compliance* at *http://www.cbp.gov/xp/cgov/import/cargo_summary/reconciliation*).

These modifications to the test are effective 30 days from the date this notice is published in the **Federal Register**.

Change of Addresses

Finally, this notice announces the new mailing address for Reconciliation submissions for importers assigned to the port of NY/Newark (port 1001) and the new e-mail address for Recon.Help. The new mailing address is: U.S. Customs and Border Protection, 1100 Raymond Blvd., Newark, NJ 07201. Participants may still transmit the ABI portion of their Reconciliations to port 1001. The new e-mail address is *Recon.Help@dhs.gov*.

Dated: August 27, 2004.

Jason P. Ahern,

Assistant Commissioner, Office of Field Operations.

[FR Doc. 04–19977 Filed 9–1–04; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Delaware & Lehigh National Heritage Corridor Commission Meeting

AGENCY: Department of Interior, Office of the Secretary.

ACTION: Notice of meeting.

SUMMARY: This notice announces an upcoming meeting of the Delaware & Lehigh National Heritage Corridor Commission. Notice of this meeting is required under the Federal Advisory Committee Act (Pub. L. 92–463).

Meeting Date and Time: Friday, September 10, 2004, time 1:30 p.m. to 4 p.m.

Address: Blue Mountain Health System Community Services Center, 217 Franklin Avenue, Palmerton, PA 18071.

The agenda for the meeting will focus on implementation of the Management Action Plan for the Delaware and Lehigh National Heritage Corridor and State Heritage Park. The Commission was established to assist the Commonwealth of Pennsylvania and its political subdivisions in planning and implementing an integrated strategy for protecting and promoting cultural, historic and natural resources. The Commission reports to the Secretary of the Interior and to Congress.

FOR FURTHER INFORMATION CONTACT: C. Allen Sachse, Executive Director, Delaware & Lehigh National Heritage Corridor Commission, 1 South Third Street, 8th Floor, Easton, PA 18042; (610) 923–3548.

SUPPLEMENTARY INFORMATION: The Delaware & Lehigh National Heritage Corridor Commission was established by Public Law 100–692, November 18, 1988, and extended through Public Law 105–355, November 13, 1998.

Dated: August 26, 2004.

C. Allen Sachse,

Executive Director, Delaware & Lehigh National Heritage Corridor Commission.

[FR Doc. 04–20013 Filed 9–1–04; 8:45 am]

BILLING CODE 6820–PE–M

DEPARTMENT OF THE INTERIOR

Geological Survey

Advisory Committee on Water Information (ACWI)

AGENCY: United States Geological Survey, Interior.

ACTION: Notice of an open meeting of the Advisory Committee on Water Information (ACWI).

SUMMARY: Notice is hereby given of a meeting of the ACWI. This meeting of the ACWI is to discuss broad policy-related topics relating to national water initiatives, and to hear reports from ACWI subgroups. The proposed agenda will include a series of discussions concerning various U.S. Government policies and programs related to the development and dissemination of water information.

The ACWI has been established under the authority of the Office of Management and Budget Memorandum 92–01 and the Federal Advisory Committee Act. The purpose of the ACWI is to provide a forum for water-information users and professionals to advise the Federal Government of activities and plans that may improve the effectiveness of meeting the Nation's water information needs. More than 30 organizations were invited by the Secretary of the Interior to be representatives on ACWI. These include Federal departments, State, local, and tribal government organizations, industry, academia, agriculture, environmental organizations, professional societies, and volunteer groups.

DATES: The formal meeting will convene at 8:30 a.m., on September 14, 2004, and