proposed administrative agreement pursuant to section 122(h) of CERCLA, 42 U.S.C. 9622(h), for recovery of response costs concerning the City Chemical Corporation site (''Site'') located in Hudson County, Jersey City, New Jersey. The settlement requires the settling parties, City Chemical Corporation and Peter Wolpert, the former Site-operators, and City Chemical, LLC, City Chemical Corporation's corporate successor, to pay $300,000 in reimbursement of EPA's response costs at the Site. The settlement includes a covenant not to sue the settling parties pursuant to sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a), in exchange for their payment of monies. For 30 days following the date of publication of this notice, EPA will receive written comments relating to the settlement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations that indicate that the proposed settlement is inappropriate, improper or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region II, 290 Broadway, New York, New York 10007–1866.

DATES: Comments must be submitted on or before February 10, 2003.

ADDRESSES: The proposed settlement is available for public inspection at EPA Region II offices at 290 Broadway, New York, New York 10007–1866.

Comments should reference the City Chemical Corporation Site located in Hudson County, Jersey City, New Jersey, Index No. CERCLA–02–2002–2032.

To request a copy of the proposed settlement agreement, please contact the individual identified below.

FOR FURTHER INFORMATION CONTACT: Frances M. Zizila, Assistant Regional Counsel, New Jersey Superfund Branch, Office of Regional Counsel, U.S. Environmental Protection Agency, 17th Floor, 290 Broadway, New York, New York 10007–1866. Telephone: 212–637–3135.

Dated: December 23, 2002.

George Pavlou, Director,

Emergency & Remedial Response Division.

[FR Doc. 03–393 Filed 1–8–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

PREVIOUSLY ANNOUNCED DATE AND TIME: Thursday, January 9, 2003, Meeting open to the public. This meeting was cancelled.

* * * * *

DATE AND TIME: Tuesday, January 14, 2003 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Thursday, January 16, 2003 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC (ninth floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Draft Advisory Opinion 2002–14: Libertarian National Committee, Inc. by Counsel, William W. Hall.

Administrative Matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 03–558 Filed 1–7–03; 3:53 pm]

BILLING CODE 6715–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0405]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting

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 February 10, 2003.

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: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting (OMB Control Number 0910–0437)—Extension

Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i (a), (b), and (c)) requires user facilities, manufacturers, and importers of medical devices to report adverse events involving medical devices to FDA. On December 11, 1995 (60 FR 63578 at 63597), FDA issued part 803 (21 CFR part 803) that implemented section 519 of the act. The regulation was amended to conform with the changes reflected in the 1997 FDA Modernization Act.

Information from these reports will be used to evaluate risks associated with medical devices and to enable FDA to take appropriate regulatory measures to protect the public health.

Respondents to this collection of information are businesses or other for profit and non-profit organizations including user facilities, manufacturers, and importers of medical devices.

In the **Federal Register** of Tuesday, October 1, 2002 (67 FR 61638), FDA requested public comment on the proposed collection of information. FDA received one comment, but it was not directly related to the information collection.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.19	25	1	25	1	75
803.30	1,000	3	3,000	1	3,000
803.33 FDA Form 3419	1,000	1	1,000	1	1,000
803.40	50	10	500	1	500
803.50	1,500	34	51,000	1	51,000
803.55 FDA Form 3417	700	5	3,500	1	3,500
Total					59,075

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
803.17	3,200	1	3,200	3.3	10,560
803.18[2]	39,000	1	39,000	1.5	58,500
Total					69,060

[1] There are no capitol costs or operating and maintenance costs associated with this collection of information.
[2] Include an estimated 35,000 medical device distributors. Although they do not submit medical device reports, they must maintain records of complaints.

The agency believes that the majority of manufacturers, user facilities, and importers have already established written procedures to document complaints and information to meet the medical device report (MDR) requirements as part of their internal quality control system.

Part 803 requires user facilities to report incidents where a medical device caused or contributed to a death or serious injury to the device manufacturer and to FDA (in case of death). Manufacturers of medical devices are required to report to FDA when they become aware of information indicating that one of their devices may have caused or contributed to death or serious injury or has malfunctioned in such a way that should the malfunction recur, it would be likely to cause or contribute to death or serious injury. Device importers report deaths and serious injuries to the manufacturers and FDA. Importers report malfunctions only to the manufacturers, unless they are unknown. If the manufacturer is unknown, the importer sends the reports to FDA.

The agency has estimated that on average, 1,800 entities annually would be required to establish new procedures or revise existing procedures in order to comply with MDR provisions. For those entities, a one-time burden of 10 hours is estimated for establishing written MDR procedures. The remaining manufacturers, user facilities, and importers which are not required to revise their written procedures to comply with this provision are excluded from the burden because the recordkeeping activities needed to comply with this provision are considered ''usual and customary'' under 5 CFR 1320.3(b)(2).

Dated: January 2, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–361 Filed 1–8–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0509]

International Conference on Harmonisation; Draft Guidance on the M4 Common Technical Document—Quality: Questions and Answers/ Location Issues; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of December 30, 2002 (67 FR 79639). The document announced the availability of a draft guidance entitled ''Common Technical Document—Quality: Questions and Answers/Location Issues.'' The document was published with an inadvertent error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 02–32852, appearing on page 79639 in the **Federal Register** of Monday, December 30, 2002, the following correction is made:

1. On page 79639, in the first column, in the heading of the document, ''[Docket No. 02N–0509]'' is corrected to read ''[Docket No. 02D–0509]''.

Dated: January 3, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–360 Filed 1–8–03; 8:45 am]

BILLING CODE 4160–01–S