(**Federal Register** of June 1, 2000, Vol.65, No 106, p. 35069–35090, Table 10; Guidance on Pesticide Import Tolerances and Residue Data for Imported Food). Furthermore, USDA's import statistics show that not more than 38% of beer consumed in the USA is imported and/or contains imported hops, which translates into a diet contribution from imported hops of not more than 0.0007%. For the purposes of this risk assessment, it was also demonstrated in brewing studies using hops treated with folpet at maximum label rates (range of residues: 25 to 65 ppm) and exaggerated hopping rates (0.002% or up to 2 g per liter wort) that no folpet residues could be measured in the finished beer (LOD = 0.003 ppm). Hopping rates in beer production are usually less than 0.001% in brew water (wort). Even considering that trace amounts of folpet would enter the brewing process, it will be rapidly hydrolyzed and completely degraded by the end of the beer brewing.

In view of this information and assumptions, the resulting dietary risk contribution via imported hops is negligible, even if 100% of the imported hops would be treated with folpet at maximum label rates.

ii. *Drinking water*. The potential for folpet to leach into groundwater or contaminate surface water is very limited considering that folpet is currently only registered for the use on avocados in two counties in Florida. Based on the available information, the predicted residues in drinking water do not indicate an unacceptable contribution to acute or chronic dietary exposure at this time. Since the proposed petition does not add any new uses or exposures to it, contribution of any folpet residues in drinking water to the total dietary intake is negligible.

2. *Non-dietary exposure*. Not applicable.

D. Cumulative Effects

There is a common mechanism of toxicity that folpet shares with captan with regard to its carcinogenicity in the mouse. Folpet and captan share the common metabolite, thiophosgene, which contributes to the irritancy of the duodenum in mice along with the parent compounds, leading (at dose levels above the established threshold and for administration with sufficient time) to adenomas. Thiophosgene reacts not only with thiol groups, as does folpet and captan, but also with a variety of other functional groups. This instability results in its rapid loss. The cumulative effect of captan and folpet oral exposure is of theoretical interest only, as the threshold for irritancy in the mouse duodenum is above 60 mg/kg/day (captan) or 50 mg/kg/day (folpet). If the mouse test system reflected human susceptibility, a 70 kg individual would need to consume more than 3.5 grams folpet plus captan in order to approach the NOEL of 50 mg/kg/day. Given the expected residue levels of folpet and those of captan, this is not possible.

E. Safety Determination

1. *U.S. population*. Using the exposure assumptions described above, MANA concludes that the total dietary exposure to folpet is acceptable. According to import information statistics from the USDA and under the conservative (worst-case) dietary exposure assumption described above, not more than 0.0022% of the U.S. population diet is constituted of hops, which means not more than 0.0007% can potentially be contributed to imported hops. Based on these insignificant dietary contributions, MANA considers the potential folpet residue contribution negligible, concluding that the most sensitive population group of concern are still females (15–50 years) with an aPAD of 25% and a cPAD of <1%. There is generally no concern for exposures below 100% of the PAD since it represents the level at or below which no appreciable risks to human health is posed. The upper bound calculated dietary cancer risk was 9.8×10^{-8}, based on a Q* of 0.00186 $mg/kg/day^{-1}$, which is far less than EPA's level of concern of 1×10^{-6}.

Thus, there is reasonable certainty that no harm will result to the U.S. population in general or to any of its subgroups of concern from aggregate exposure to folpet residues in or on imported hops.

2. *Infants and children*. Data from rat and rabbit development toxicity studies and rat multigeneration reproduction studies are generally used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from pre-natal and post-natal exposure to the pesticide.

FFDCA Section 408 provides that the Agency may apply an additional safety factor for infants and children to account for pre- and post-natal toxicity or incompleteness of the database. However, the toxicology database for folpet regarding potential pre- and post-natal effects in offspring is complete according to existing Agency data requirements and does not indicate any particular developmental or reproductive concerns.

EPA assigned an FQPA safety factor of 3x in the 1999 Reregistration Eligibility Decision (RED). This was based on the apparent hydrocephaly seen in New Zealand rabbits. Subsequently, additional data were provided to the Agency that showed folpet does not induce hydrocephaly. The Agency agreed with the assessment contained in the submitted document and rescinded its request for a new rabbit study. The Agency has not, as of yet, removed the FQPA 3x safety factor. A FQPA safety factor of 1x would be also consistent with that of captan. The appropriate acute Reference Dose (aRfD) for folpet, calculated with a FQPA safety factor of 1x, would be 0.01 mg/kg/day. This aRfD should be used in future assessments concerning the potential risks to infants and children. However, for the purpose of this assessment, MANA used the existing aRfD of 0.03 mg/kg/day, as it was done in the 1999 RED.

MANA concludes that there is a reasonable certainty that no harm will result to infants and children from the anticipated dietary exposure to residues of folpet and considering that the proposed import tolerance does not affect foods and beverages legally consumed by children and infants.

F. International Tolerances

Germany has established an MRL (maximum residue limit) of 120 ppm for residues of folpet in dried hops. No CODEX MRL for hops exists.

[FR Doc. 03–389 Filed 1–8–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7437–1]

Proposed CERCLA Section 122(h)(1) Administrative Agreement for Recovery of Response Costs for the City Chemical Corporation Site, Hudson County, Jersey City, NJ

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given by the U.S. Environmental Protection Agency (''EPA''), Region II, of a

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: