into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes; (6) has no side effects, even at double or tiple the normal dose of 260 ppm, and is safe for children and pregnant and nursing women; and (7) aids the growth and health of the developing fetus and cases delivery and recovery.

Part I of the consent order prohibits respondent from misrepresenting any claims that Collidal Silver or any food, dietary supplement, drug, device, or health-related service or program has been medically proven to kill disease-causing organisms or any number of infections in the body. Part II of the order requires competent and reliable scientific evidence to substantiate representations that Colloidal Silver or any covered product (1) is effective in treating 650 diseases and health-related conditions, including AIDS, allergies, anthrax, arthritis, blood poisoning, boils, wounds of the cornea, chronic fatigue, cerebral spinal meningitis, candida, cholera, colitis, cystitis, dental plaque, disabetes, diphtheria, dyesentery, enlarged prostate, gonorrhea, herpes, hepatitis, infantile diseases, lesions, leukemia, lupus, Lyme disease, parasites, rheumantism, ringworm shingles, skin cancer, staph and strep infections, stomach flu, thyroid conditions, tonsillitis, toxemia, stomach ulcers and whooping cough; (2) kills the HIV virus and can be used as an antibiotic for all acquired diseases of active AIDS; (3) is superior to antibiotics in killing disease-causing organisms and the treatement of burns; (4) protects and strengthens the immune system; (5) can safely be used on open wounds, sprayed into the eye, injected, used orally, vaginally, anally, atomized or inhaled into the nose or lungs and dropped into the eyes; (6) has no side effects, even at double or tripe the normal dose of 260 ppm, and is safe for children and pregnant and nursing women; (7) aids the growth or health of the developing fetus or eases delivery or recovery; (8) is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or (9) has any health, performance, safety, or efficacy benefits.

Part III of the order prohibits respondent from misrepresenting, including by means of metatags, the existence, contents or interpretation of any test, study, or research. Part IV of the order permits respondent to make certain claims for drugs or dietary supplements, respectively, that are permitted in labeling under laws and/or regulations administered by the U.S. Food and Drug Administration.

Part V and VI of the order require respondents to offer refunds to all of his past consumers and wholesale purchasers of Colloidal Silver. Part VII requires respondent to file a sworn affidavit with the Commission concerning his compliance with the refund provisions.

The remainder of the order contains standard requirements that respondent maintain advertising and any materials relied upon as substantiation for any representation covered by substantiation requirements under the order; distribute copies of the order to certain company officials and employees; notify the Commission of any change in the business entity that may affect compliance obligations under the order; and file one or more reports detailing his compliance with the order. Part XV of the order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

This order will resolve the claims alleged in the complaint against the named respondent. It is not the Commission's intent that acceptance of this consent agreement and issuance of a decision and order will release any claims against any unnamed persons or entities associated with the conduct described in the complaint.

Effective Date of Order and Opportunity for Public Comment

The Commission issued the Complaint and the Decision and Order, and served them upon the Respondent, at the same time it accepted the Consent Agreement for public comment. As a result of this action, the Order has already become effective. In August 1999, the Commission adopted procedures to allow for immediate effectiveness of an Order prior to a public comment period. The Commission announced that it ''contemplates doing so only in exceptional cases where, for example, it believes that the allegedly unlawful conduct to be prohibited threatens substantial and imminent public harm.'' 64 FR 46267 (1999).

This case is an appropriate one in which to issue a final order before receiving public comment because the complaint alleges that the respondent made false and unsubstantiated health and safety claims of a serious nature, and the respondent continued to make the challenged claims after signing the consent agreement. Accordingly, the Commission believes it is important to prohibit the respondent from making these claims as quickly as possible.

The Order has also been placed on the public record for 30 days for receipt of comments by interested persons, and comments received during this period will become part of the public record. Thereafter, the Commission will review the Order, and may determine, on the basis of the comments or otherwise, that the Order should be modified.[1]

The Commission anticipates that the order, as issued, will satisfactorily address the deceptive practices alleged in the Complaint. The purpose of this analysis is to invite public comment on the Order to aid the Commission in determining whether to modify the Order in any respect, and is not intended to constitute an official interpretation of the agreement and order, or to modify in any way their terms.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 02–5329 Filed 3–5–02; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Amendment of Statement of Organization, Functions, and Delegations of Authority for the Office of Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office for Human Research Protections.

ACTION: Notice.

SUMMARY: This amendment describes modifications in the functions of the Immediate Office of the Director, Office for Human Research Protection, (OHRP), to include international functions, changes the name and functions of the former Division of Policy and Assurance, establishes a Division of Policy Planning and Special Projects, and updates the delegations of authority.

Part A, Office of the Secretary (OS), of the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (DHHS), Chapter AC, Office of Public Health and Science (OPHS), Office for Human Research Protections (OHRP), as last amended at

[1] If the Respondent does not agree to such modifications, the Commission may (1) initiate a proceeding to reopen and modify the Order in accordance with Rule 3.72(b), 16 CFR 3.72(b), or (2) commence a new administrative proceeding by issuing an administrative complaint in accordance with Rule 3.11, 16 CFR 3.11. *See* 16 CFR 2.34(e)(2).

65 FR 37136, dated June 13, 2000, is being amended as following:

I. Part L, description of OHRP, is deleted in its entirety and replaced with the following:

L. Office for Human Research Protections (ACN)—The Office for Human Research Protections (OHRP) fulfills responsibilities set forth in the Public Health Service Act. These include: (1) Providing leadership for human research subjects protections within the Department of Health and Human Services (DHHS) and for the U.S. Government in cooperation with other Federal Agencies; (2) developing and monitoring as well as exercising compliance oversight relative to DHHS regulations for the protection of human subjects in research conducted or supported by any component of the Department of Health and Human Services; (3) promoting and coordinating appropriate DHHS regulations, policies, and procedures both within DHHS and in coordination with other Departments and Agencies in the Federal Government; (4) establishing criteria for approval of assurances of compliance for the protection of human subjects with both domestic and foreign institutions engaged in DHHS-conducted or supported research involving human subjects; (5) conducting programs of clarification and guidance for both the Federal and non-Federal sectors with respect to the involvement of humans in research; and directing the development and implementation of educational and instructional programs and generating educational resource materials; (6) evaluating the effectiveness of DHHS policies and programs for the protection of human subjects; (7) serving as liaison to Presidential, Departmental, Congressional, interagency, non-governmental, and international commissions and boards to examine ethical issues in medicine and research and exercises leadership in identifying and addressing such ethical issues; and (8) promoting the development of approaches to enhance and improve methods, particularly quality improvement at the institutional level, to avoid unwarranted risks to humans participating as subjects in research covered by applicable statutes.

II. Amend Part L, subpart 1, by replacing it in its entirety with the following:

1. Office of the Director (ACN1)—The Office of the Director reports to the Assistant Secretary for Health, and (1) provides leadership within DHHS on ethical and other issues associated with protection of human subjects in research; (2) supervises and manages the development and promulgation of policies, procedures, and plans for meeting the responsibilities set forth above; (3) advises the Secretary, Assistant Secretary for Health and other DHHS officials on ethical issues pertaining to medical, biomedical, behavioral, social, health services, public health and other research, including all issues relative to the implementation of DHHS Regulations for the Protection of Human Subjects; (4) directs the development, implementation, and compliance oversight activities for DHHS Regulations and for the protection of human subjects; (5) establishes criteria for approval of and exercises oversight of assurances of compliance for protection of human subjects in all areas of human subject research; (6) maintains liaison and coordinates policy implementation with components throughout DHHS that conduct and support research involving human subjects; (7) directs the implementation of quality improvement programs through the development and implementation of educational and instructional programs, including generation of resource materials relating to the responsibilities of the research community for the protection of human subjects; and (8) engages in international activities related to human research subject protections, particularly global efforts to achieve harmonization of policies and procedures and for the building of global capacity to enhance protections for human subjects participating in research.

III. Amend Part L, subpart 2, by replacing it in its entirety with the following:

2. Division of Assurances and Quality Improvement (ACN 2)—(1) Receives and approves assurances of compliance from research entities; (2) provides liaison, guidance and regulatory interpretation to research entities, investigators, Federal officials and the public; (3) operates and maintains a registration system for institutional review boards; (4) maintains and modifies as necessary assurance mechanisms and procedures; (5) develops and conducts quality improvement activities to improve protections for human research subjects; and (6) develops and implements new procedures and instruments to ensure DHHS human subjects protections regulations are appropriately and effectively applied in a manner consistent with the changing needs of the Federal Government, the research community and society.

III. Amend Part L, by adding a subpart 5 as follows:

5. Division of Policy Planning and Special Projects (ACN 5)—(1) Maintains, develops, promulgates, and updates policy and guidance documents regarding regulatory requirements, and ethical issues for biomedical and behavioral research involving human subjects; (2) coordinates appropriate DHHS regulations, policies and procedures with other Departments and Agencies in the Federal Government; (3) conducts public outreach and education or information programs to promote and enhance public awareness of the activities of OHRP and human subject protections; (4) provides staff support to the National Human Research Protections Advisory Committee; (5) provides staff support to the Human Subjects Research Subcommittee, Committee on Science, National Science and Technology Council; (6) organizes and coordinates consultations with panels of experts for research involving prisoners and children, when required by DHHS regulations for the protection of human subjects at 45 CFR 46.306 and 46.407, respectively; (7) coordinates responses to requests for information, technical assistance and guidance from Congress, other DHHS agencies, other Federal Departments and agencies, and non-governmental entities; (8) coordinates responses to requests for OHRP documents and information under the Freedom of Information act; and (9) manages and conducts special projects as requested by the Director, OHRP.

IV. Amend Part E, Chapter AC as follows:

E. Delegation of Authority: The Secretary's authority under Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) has been delegated to the Assistant Secretary for Health, 44 Fed. Reg. 46318 (August 7, 1979). Authority under Section 491 of the Public Health Service Act (42 U.S.C. 289) is re-delegated to the Director, OHRP, to perform all of the authorities previously delegated to the Assistant Secretary for Health, 44 Fed. Reg. 46318. Consistent with the prior delegation of authority to the Assistant Secretary for Health, this re-delegation to the Director, OHRP, excludes the authorities to promulgate regulations, submit reports to the President or the Congress, approve organizational changes, and establish and select members of national advisory councils and boards. Previous delegations and re-delegations of authority under section 491 of the PHS act are superceded.

V. Amend Part G, Chapter AC as follows:

G. Effective Date: The effective date of the foregoing amendments to the

organization, functions and delegations of authority for the Office for Human Research Protections is March 18, 2002.

Dated: February 28, 2002.

Eve E. Slater,

Assistant Secretary for Health.

[FR Doc. 02–5303 Filed 3–5–02; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Oak Ridge Reservation Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Oak Ridge Reservation Health Effects Subcommittee (ORRHES).

Time and Date: 12 p.m.—8 p.m., March 26, 2002.

Place: YWCA of Oak Ridge, 1660 Oak Ridge Turnpike, Oak Ridge, Tennessee, 37830. Telephone: (865) 482–2008.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Background: A Memorandum of Understanding (MOU) signed in October 1990 and renewed in September 2000 between ATSDR and DOE, delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles. In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 2000, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS has delegated program responsibility to CDC.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, pertaining to CDC's and ATSDR's public health activities and research at this DOE site. Activities shall focus on providing the public with a vehicle to express concerns and provide advice and recommendations to CDC and ATSDR. The purpose of this meeting is to receive updates from ATSDR and CDC, and to address other issues and topics, as necessary.

Matters To Be Discussed: The agenda includes a discussion of the public health assessment process, updates from the Public Health Assessment, Health Needs Assessment, Agenda, and Outreach and Communications Workgroup. Agenda items are subject to change as priorities dictate.

FOR MORE INFORMATION CONTACT: La Freta Dalton, Designated Federal Official, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE, M/S E–54, Atlanta, Georgia 30333, telephone 1–888–42–ATSDR(28737), fax 404/498–1744.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 27, 2002.

Alvin Hall,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02–5279 Filed 3–5–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Childhood Lead Poisoning Prevention: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Advisory Committee on Childhood Lead Poisoning Prevention.

Time and Date: 8:30 a.m.–5:00 p.m., March 12, 2002.

Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202, telephone 410/539–2000.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 90 people.

Purpose: The Committee shall provide advice and guidance to the Secretary; the Assistant Secretary for Health; and the Director, CDC, regarding new scientific knowledge and technological developments and their practical implications for childhood lead poisoning prevention efforts. The Committee shall also review and report regularly on childhood lead poisoning prevention practices and recommend improvements in national childhood lead poisoning prevention efforts.

Matters to be Discussed: Agenda items include: Updates on Primary Prevention issues, Medicaid Targeted Screening issues, and Discussions on Future of Lead Poisoning Prevention Research, Revision of Adopted Children Letter, and Recent International Lead Activities by CDC's Lead Poisoning Prevention Branch. Agenda items are subject to change as priorities dictate.

Opportunities will be provided during the meeting for oral comments. Depending on the time available and the number of requests, it may be necessary to limit the time of each presenter.

Contact Person for More Information: Gary Noonan, Acting Chief, Lead Poisoning Prevention Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 1600 Clifton Road, NE, M/S E–25, Atlanta, Georgia 30333, telephone 404/498–1442, fax 404/498–1444.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the