

public health capacity development; (5) provides on-site epidemiologic consultation to national ministries of health and international organizations as required; (6) provides on-site technical assistance, consultation, and training to other countries and international organizations in applied communications, publications management, health information systems development and management, and health economics.

Effective Date: September 19, 1997.

David Satcher,

Director.

[FR Doc. 97-25946 Filed 9-30-97; 8:45 am]

BILLING CODE 4160-18-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0390]

Guidance for the Submission of 510(k)'s for Solid State X-Ray Imaging Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices." The draft guidance is neither final nor is it in effect at this time. This draft guidance applies to a new category of medical devices, Solid State X-ray Imagers (SSXI), and is currently available for comment. This draft guidance is intended to provide guidance to the significant number of premarket (510(k)) submissions resulting from this new technology. The draft guidance addresses the type of data needed by the Center for Devices and Radiological Health (CDRH) to establish the substantial equivalence of an SSXI to a previously cleared conventional radiographic film/screen system, fluoroscopic image intensified imaging system, or SSXI.

DATES: Written comments by December 30, 1997.

ADDRESSES: Submit written requests for single copies of "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" to the Division of Small Manufacturers Assistance (HFZ-200), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that

office in processing your requests. Submit written comments on "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" to the contact person listed below.

FOR FURTHER INFORMATION CONTACT:

Robert J. Doyle, Center for Devices and Radiological Health (HFZ-476), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-1212.

SUPPLEMENTARY INFORMATION: The final version of this guidance will provide instruction concerning the type of data needed by CDRH to clear a new category of medical devices, SSXI's, for marketing via section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)). This new category of medical devices is intended to replace conventional x-ray film/screen systems and image intensifier based fluoroscopic and image recording systems. As solid state imaging technology continues to progress, FDA anticipates a significant number of premarket (510(k)) submissions to be based on this new technology. By issuing the guidance, FDA hopes to receive a larger percentage of complete premarket submissions upon submittal. This will avoid the need for additional information requests which are time consuming for both FDA and manufacturers.

Under the Medical Device Amendments to the act, a device may be cleared for marketing via a 510(k) premarket notification. To do so, the device must be shown to be substantially equivalent to a legally marketed predicate device. This guidance sets forth nonclinical and clinical data necessary to establish the substantial equivalence of the new device to the identified predicate device(s).

This draft guidance document represents the agency's current thinking on the data necessary to establish the substantial equivalence of SSXI to a previously cleared device. 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 statute, regulations, or both.

Interested persons may, on or before December 30, 1997, submit to the contact person (address above) written comments regarding this draft guidance. Persons with access to the Internet may obtain the draft guidance via the World Wide Web (WWW) at "http://www.fda.gov/cdrh".

Dated: July 31, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97-25992 Filed 9-30-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention; Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 62 FR 46751, dated September 4, 1997) is amended to reflect the organizational structure for mine safety and health research functions within the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention.

Section C-B, *Organization and Functions*, is hereby amended as follows:

After the functional statement for the *Contracts and Purchases Branch (CA582)*, *Procurement and Grants Office (CA58)*, *Office of Program Support (CA5)*, insert the following:

Contracts Management Branch (Pittsburgh) (CA583). (1) Provides leadership, direction, procurement options and approaches in developing specifications/statements of work and contract awards; (2) Executes research and development contracts for all of NIOSH.

Revise the functional statement for the *Office of Administrative and Management Services (CC11)* to insert the following as item (4) and renumber the remaining items accordingly: (4) provides management information, advice, and guidance to CDC/OPS regarding the conduct and the evaluation of Staff Office procurement activities with respect to their effectiveness in meeting NIOSH's administrative and programmatic needs.

After the functional statement for the *Office of Administrative and Management Services (CC11)*, insert the following:

Administrative Services Branch (Pittsburgh) (CC112). (1) Provides basic facilities operations, maintenance, and

support functions for the offices, laboratories, and grounds at the Pittsburgh Research Laboratory; (2) provides access to library and information services for Pittsburgh laboratory personnel; (3) facilitates procurement support for the Laboratory; (4) coordinates Institute activities and overall operations with the facility management activities of the other Agencies operating at the Bruceton Research Center.

After the functional statement for the *Administrative Services Branch (Cincinnati) (CC113)*, insert the following:

Administrative Services Branch (Spokane) (CC114). (1) Provides basic facilities operations, maintenance, and support functions for the offices, laboratories, and grounds at the Spokane Research Laboratory; (2) provides access to library, information services, and computer access to the CDC network for Spokane Research Laboratory personnel; (3) provides site-wide safety and health program support, site environmental compliance activities, employee assistance programs, and employee wellness programs; (4) provides procurement and budget support for the Laboratory; (5) provides material management functions, including inventory control for accountable property, and warehouse supply for daily operations.

After the functional statement for the *Management Systems Branch (CC115)*, insert the following:

Procurement Branch (Pittsburgh) (CC116). (1) Plans, directs, and conducts the acquisition of equipment, materials, and non-personnel services in support of the NIOSH Pittsburgh operations; (2) executes contracts for repairs, and capitol improvements to NIOSH Pittsburgh facilities.

After the functional statement for the *Regional Operations Branch (CC134)*, insert the following:

Pittsburgh Research Laboratory (CC2). (1) Provides leadership for prevention of work-related illness, injury, and fatalities of miners; (2) carries out the surveillance of fatal and non-fatal traumatic injuries, occupational diseases, health and safety hazards, and the use of control technology and protective equipment for prevention of injury and disease in mining; (3) conducts research on the measurement, monitoring, and control of dust and other toxic substances to which miners may be exposed; (4) conducts laboratory and field research to evaluate and control hearing loss and occupational noise exposure in mining; (5) conducts field investigations and laboratory studies on mining injuries and the

means for their prevention; (6) conducts laboratory and field investigations to better understand the causes of catastrophic events that may lead to fatalities, such as fires, explosions, and structural or ground failures; (7) develops sensors, predictive models, and engineering controls to reduce miners risk for injury or death; (8) translates research findings, new control technology concepts, and newly identified approaches to health and safety problems affecting miners into usable effective interventions; (9) utilizes the unique facilities and resources of the Laboratory as a National resource in collaboration with other NIOSH units as well as other Departments and Agencies of the government.

Surveillance, Statistics, and Research Support Activity (CC22). (1) Collects and analyzes health and safety data related to mining occupations in order to report on the overall incidence, prevalence and significance of occupational safety and health problems in mining; (2) describes trends in incidence of mining-related fatalities, morbidity, and traumatic injury; (3) conducts surveillance on the use of new technology, the use of engineering controls, and the use of protective equipment in the mining sector; (4) coordinates surveillance activities with other NIOSH surveillance initiatives; (5) provides statistical and computer support for surveillance and research activities of the Laboratory; (6) analyzes and assists in the development of research protocols for developing studies; (7) conducts mining-relevant risk analyses and assists with interpretations for development of NIOSH policy or documents.

Extramural Coordination and Information Dissemination Activity (CC23). (1) Collaborates with research staff to translate findings from laboratory research to produce compelling products that motivate the mining sector to engage in improved injury control and disease prevention activities; (2) incorporates recommended control technologies, work practices, and findings of technological feasibility into NIOSH policy documents and testimony; (3) coordinates with other health communication, health education, and information dissemination activities within the Institute to ensure that mining research information is effectively integrated in the NIOSH dissemination and intervention strategies; (4) serves as the laboratory focal point for partnerships with labor, industry and academia and other government agencies to foster mission-

relevant responsive research; (5) assists in the development of mission-relevant CRADAs and patents; (6) coordinates mission-relevant technical assistance and response activities; (7) coordinates mining grants and cooperative agreements with the NIOSH Office of Extramural Coordination and Special Projects.

Dust and Toxic Substance Control Branch (CC24). (1) Develops, plans, and implements a program of research to develop or improve personal and area direct reading instruments for measuring mining contaminants including but not limited to respirable dust, silica, and other toxic substances and mixtures; (2) conducts field tests, experiments, and demonstrations of new technology for monitoring and assessing mine air quality; (3) designs, plans, and implements laboratory and field research to develop airborne hazard reduction control technologies; (4) carries out field surveys in mines to identify work organization strategies that could result in reduced dust or toxic substance exposure; (5) evaluates the performance, economics, and technical feasibility of engineering control strategies, novel approaches, and the application of new or emerging technologies for underground and surface mine dust and toxic substance control systems; (6) develops and evaluates implementation strategies for using newly developed monitors and control technology for exposure reduction or prevention.

Hearing Loss Prevention Branch (CC25). (1) Plans and conducts laboratory and field research on noise-induced hearing loss in miners; (2) conducts field dosimetric and audiometric surveys to assess the extent and severity of the problem and to identify those mining segments in greatest need of attention and to objectively track progress in meeting loss prevention goals; (3) conducts field and laboratory research to identify noise generation sources and to identify those areas most amenable to intervention activities; (4) develops, tests, and demonstrates new control technologies for noise reduction; (5) evaluates technical and economic feasibility of controls; (6) develops, evaluates, and recommends implementation strategies to promote the adoption and use of noise reduction technology.

Mining Injury Prevention Branch (CC26). (1) Conducts laboratory, field, and computer modeling research to focus on human physiological capabilities and limitations and their interactions with mining jobs, tasks, equipment, and the mine work environment; (2) assesses the health and

safety relevance of mining equipment design features using scientific and engineering techniques, and analyses of reported case-studies of mining incidents that lead to traumatic injuries or fatalities; (3) designs and conducts epidemiological research studies to identify and classify risk factors that cause, or may cause, traumatic injuries to miners; (4) designs, builds, and tests proposed interventions, including demonstrations of proposed technologies using laboratory mock-ups, full-scale demonstrations at the laboratory's experimental mines, or through field evaluation in operating mines; (5) evaluates and recommends implementation strategies for injury prevention and control technologies developed by the Laboratory.

Disaster Prevention and Response Branch (CC27). (1) Conducts laboratory and field investigations of catastrophic events such as explosions and catastrophic structural or ground failures to better understand cause and effect relationships that initiate such events; (2) designs and implements appropriate intervention strategies; (3) develops, tests, and promotes the use of disaster prediction and risk evaluation systems for control or reduction of risk; (4) develops criteria and tests for explosives to determine their suitability for mine use and transportation; (5) evaluates and recommends implementation strategies for disaster prevention; (6) assists in the development and evaluation of curricula for mine rescue, firefighting, and the use of life support (self-rescuer) equipment, in conjunction with other health education, health communication, and other information and education activities of the Institute.

Following the functional statement for the *Division of Surveillance, Hazard Evaluations, and Field Studies (CC5)*, insert the following:

Spokane Research Laboratory (CC6). (1) Provides leadership for prevention of work-related illness, injury, and death in the extractive industries in the Western United States; (2) conducts surveillance and tracks trends of fatal and non-fatal traumatic injuries, occupational diseases, health and safety hazards, and the use of control technology in the extractive industries, with a focus on unique Western issues such as those associated with deep metal mines, Western coal mines, and precious metal deposits; (3) conducts field investigations, health hazard evaluations, and laboratory studies of occupational diseases, injuries, and fatalities with focus on western-area mineral-extractive industries; (4) conducts laboratory and field

investigations to better understand the causes of catastrophic events that may lead to multiple injuries and fatalities, such as collapse of underground workings, massive slope failures, and the collapse of mining facilities; (5) develops, tests, and demonstrates sensors, predictive models, and engineering control technologies to reduce miners risk for injury or death; (6) develops and recommends appropriate criteria for new standards, NIOSH policy, documents, or testimony related to health and safety in the extractive industries.

Extramural Coordination and Information Dissemination Activity (CC62). (1) Coordinates with other education and information dissemination activities within the Institute to assure that coordinated and comprehensive mining research information is effectively integrated into the NIOSH dissemination and intervention strategies; (2) serves as the laboratory focal point for partnerships with labor, industry and academia involved with Western extractive industries; (3) assists in the development of mission-relevant CRADAs and patents; (4) coordinates mission-relevant technical assistance and response activities for the western United States.

Mining Surveillance and Statistics Support Activity (CC63). (1) Describes trends in incidence of mining-related fatalities, morbidity, and traumatic injury; (2) conducts surveillance on the use of new technology and the use of engineering controls; (3) coordinates the surveillance activities with other Institute-wide surveillance initiatives; (4) provides statistical support for all surveillance and research activities of the Laboratory; (5) assists in the development of research protocols; (6) communicates the results of surveillance activities to researchers to assist in the planning and prioritization of future studies.

Mining Injury and Disease Prevention Branch (CC64). (1) Designs and conducts field and laboratory research studies to identify and classify risk factors that cause, or may cause, traumatic injuries or illness to miners; (2) designs, builds, and tests proposed interventions to reduce risk of injury or disease, and conducts demonstrations of proposed control technologies; (3) assesses the health and safety implications of mining equipment design features using scientific and engineering techniques; (4) evaluates and recommends implementation strategies for injury and disease prevention and the effective utilization

of control technologies developed by the laboratory.

Catastrophic Failure Detection and Prevention Branch (CC65). (1) Conducts laboratory and field investigations of catastrophic events such as collapse of underground workings, massive slope failures, collapse of mine facilities, or other events that lead to traumatic injuries or fatalities; (2) develops computer visualization models to simulate mine conditions and test alternative mining methods and approaches for risk reduction and catastrophic failure prevention; (3) develops, tests, and promotes the use of catastrophic failure prediction and risk evaluation systems; (4) evaluates and recommends implementation strategies for catastrophic failure prevention.

Dated: September 4, 1997.

David Satcher,

Director.

[FR Doc. 97-25947 Filed 9-30-97; 8:45 am]

BILLING CODE 4160-18-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of a Draft Revised Recovery Plan for the Chittenango Ovate Amber Snail (*Novisuccinea Chittengoensis*) for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: The U.S. Fish and Wildlife Service announces the availability for public review of a draft revised Recovery Plan for the Chittenango ovate amber snail (*Novisuccinea Chittengoensis*). The Chittenango ovate amber snail is a terrestrial species with only one known population, which is located in the Chittenango Falls State Park in Madison County, New York. It was listed as a threatened species in July 1978, and the initial recovery plan was completed in March 1983. This species was listed due to its rarity and population decline; since listing, habitat protection and captive propagation activities have been implemented, but the species' status remains exceedingly precarious. The primary threat to the Chittenango ovate amber snail is considered to be over-competition by an introduced snail, *Succinea* sp B. Additionally, potential threats persist from habitat changes and inadvertent human disturbance. The revised recovery objective for this species is to stabilize it by maintaining, to the extent possible, the extant Chittenango ovate