## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### National Institute for Occupational Safety and Health; Draft Document ''Review of NIOSH Report to Congress on Workers' Home Contamination Study Conducted Under the Workers' Family Protection Act (29 U.S.C. 671a)''

**AGENCY:** National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

**ACTION:** Request for comments.

**SUMMARY:** NIOSH is seeking public comments on the draft document ''Review of NIOSH Report to Congress on Workers' Home Contamination Study conducted under the Workers' Family Protection Act (29 U.S.C. 671a)'', provided in this announcement. The Workers' Family Protection Task Force was chartered in 1994 to review the NIOSH Report and to make recommendations to Congress for a research agenda that federal agencies might implement to investigate the types and magnitude of workplace-transported (''take-home'') exposures and their potential adverse consequences among workers' family members. This document represents the Task Force's commentary on the NIOSH Report, identifies gaps in current knowledge of take-home exposures and related health effects, and presents a prioritized agenda for federally-sponsored research. In particular, comments are being sought regarding additional data needs not identified by the Task Force and comments on the recommended investigative strategy proposed by the Task Force for use in meeting data gaps.

**DATES:** Written comments to this notice should be submitted to Diane Miller, NIOSH Docket Office, 4676 Columbia Parkway, Mailstop C–34, Cincinnati, Ohio 45226. Comments must be received on or before April 6, 1998. Comments may also be submitted by email to: dmm2@cdc.gov as WordPerfect 5.0, 5.1/5.2, 6.0/6.1, or ASCII files.

**FOR FURTHER INFORMATION CONTACT:** Technical information may be obtained from Elizabeth Whelan, 4676 Columbia Parkway, Mailstop R–15, Cincinnati, Ohio 45226, telephone 513–841–4437.

**SUPPLEMENTARY INFORMATION:** The following is the complete text of the draft document for public comment ''Review of NIOSH Report to Congress on Workers' Home Contamination Study conducted under the Workers' Family Protection Act (29 U.S.C. 671a)'' and the NIOSH response to the Task Force report.

**SUMMARY:** At the request of the U.S. Congress, the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health (NIOSH) issued a report in 1995 entitled: ''Report to Congress on Workers' Home Contamination Study Conducted Under the Workers' Family Protection Act.'' This Report was prepared in response to the 1992 Workers' Family Protection Act (Pub. L. 102–522, 29 U.S.C. 671) which included a request to NIOSH to conduct a study to ''evaluate the potential for, prevalence of, and issues related to the contamination of workers' homes with hazardous chemicals and substances * * * transported from the workplaces of such workers.''

The NIOSH Report chronicled the history of workplace-transported exposures and associated health risks worldwide, primarily during the 20th century. The approach taken by NIOSH was to describe health hazards associated with readily identifiable agents that have unambiguous routes of exposure, that is, intentional transport of workplace materials, contamination of workers' clothing or external body surfaces (skin, hair), family members visiting the workplace, improper storage of hazardous agents, and as a result of cottage industries.

The Workers' Family Protection Task Force was chartered in 1994 to review the NIOSH Report and to make recommendations to Congress for a research agenda that federal agencies might implement to investigate the types and magnitude of workplace-transported (''take-home'') exposures and their potential adverse consequences among workers' family members. This document represents the Task Force's commentary on the NIOSH Report, identifies gaps in current knowledge of take-home exposures and related health effects, and presents a prioritized agenda for federally-sponsored research.

The Task Force noted that the NIOSH Report covered a wide range of literature, largely describing conditions that occurred during the 1930s–1960s. Prominent examples of take-home hazards from the workplace included poisoning from lead and beryllium, and exposure to asbestos. The Task Force noted that the Report appeared to cover available literature in a thorough manner. However, much of the literature represents anecdotal accounts of hazardous take-home exposures and subsequent illness in workers' family members. No comprehensive studies have documented the effectiveness of current workplace control programs for preventing the transport of toxic substances into homes. In addition, there is a conspicuous absence of systematic research regarding the extent of the problem and therefore no quantification of the burden of disease caused by these exposures or the burden that is likely to occur in future years. The Task Force also noted an inadequate discussion of two categories of exposure, infectious agents transmitted in biological fluids and radioactive substances.

The Task Force noted the presence of important gaps in knowledge that hinder a clear understanding of the magnitude of take-home exposures and potentially associated health consequences. For example, information is lacking on the types and levels of take-home exposures that are currently occurring in the U.S., the size and demographic composition of the populations at risk for exposure, types of illnesses associated with take-home exposures, and adequacy of exposure control methods in the workplace and in the home. Some states have reporting systems for recognized potential take-home toxicants such as lead. However, even in such surveillance systems, reporting suffers from incompleteness and lack of standardization. With these knowledge gaps, it is currently not possible to estimate the magnitude of the public health threat created by take-home exposures, nor is it possible to predict the future risks that will occur from transported toxic agents. Difficulties in determining potential hazards will likely increase in the future as new materials are introduced into the workplace.

To address deficiencies in knowledge on take-home exposures, the Task Force recommends the following prioritized Research Agenda for which funding could be provided from federal and other governmental sources and, in some cases, from the private sector:

- Characterization of the extent of home contamination with recognized workplace toxicants, including, but not restricted to: toxic metals (e.g., lead, beryllium), pesticides, and dusts (e.g., asbestos);
- Identification of populations at greatest risk of exposure to known and suspected take-home toxicants;
- Assessment of adverse health effects potentially related to take-home exposures, including considerations of previously established adverse effects and newer or less well-studied associations, such as the consequences

of transmitting infectious agents and radioactive substances into the home;

- Identification of previously unrecognized toxic exposures that potentially place workers' family members at risk for health impairment; and
- Assessment of the effectiveness of take-home exposure prevention and remediation methods, including decontamination procedures.

The Task Force recommends that this proposed Research Agenda be given full consideration by NIOSH under the Institute's National Occupational Research Agenda (NORA). The Task Force also noted that existing federal statutes apply to take-home contamination in a narrow manner, either because of substance-specific language or restrictive enforcement priorities. Moreover, the Workers' Family Protection Act (WFP Act) did not anticipate revisions to the existing statutory authority of the federal agencies that may be involved in take-home contamination issues. None will be needed if federal and State agencies take advantage of their existing statutory authority to promulgate and enforce standards and regulations that are responsive to the hazardous conditions identified by the Research Agenda developed by this Task Force. Revision of these statutes to authorize the prevention and remediation of take-home contamination, especially through revision of the prioritization schemes used by governmental agencies, such as the Environmental Protection Agency, should be considered by Congress only if the agencies find it difficult to respond effectively to the Research Agenda.

## Introduction

At the request of the U.S. Congress, the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health issued a report in 1995 entitled: ''Report to Congress on Workers' Home Contamination Study Conducted Under the Workers' Family Protection Act.'' This report (henceforth referred to as the ''NIOSH Report'') was prepared in response to the 1992 Workers' Family Protection Act (Public Law 102–522, 29 U.S.C. 671) which included a request to NIOSH to conduct a study to ''evaluate the potential for, prevalence of, and issues related to the contamination of workers' homes with hazardous chemicals and substances * * * transported from the workplaces of such workers.''

The NIOSH Report chronicled the history of workplace-transported exposures and associated health risks worldwide, primarily during the 20th century. The approach taken by NIOSH was to describe health hazards associated with readily identifiable agents that have unambiguous routes of exposure, that is, intentional transport of workplace materials, contamination of workers' clothing or external body surfaces (skin, hair), family members visiting the workplace, improper storage of hazardous agents, and as a result of cottage industries. Prominent toxic exposures included beryllium, asbestos, lead, and pesticides for which clear evidence of exposure-related sequelae had been established. Reports of exposures and risks from other agents, such as asthmagens, estrogenic substances, and infectious agents, were generally more sporadic in the literature and thus received less attention. Methods to control exposures at the workplace and in the home were also summarized and linked to specific agents.

The Workers' Family Protection Task Force was chartered in 1994 to review the NIOSH Report and to make recommendations to Congress for a research strategy that federal agencies might implement to investigate the types and magnitude of workplace-transported (''take-home'') exposures and their potential adverse consequences among workers' family members.

## Purpose

This document represents the Task Force's commentary on the NIOSH Report, identifies gaps in current knowledge of take-home exposures and related health effects, and presents a prioritized agenda for federally-sponsored research. Development of a Research Agenda to address exposure and health hazards potentially posed by take-home exposures was the Task Force's principal objective. A final section of this report is devoted to legal and policy considerations. This section was included by the Task Force to assist the Secretary of Labor in fulfilling the requirements specified under subsection (d) of the Workers' Family Protection Act, notably to assess the information developed under subsection (c) of the Act in determining additional enforcement and regulatory needs.

## Commentary on the NIOSH Report

The NIOSH Report contains a substantial amount of information culled from the available literature, primarily published reports in medical and industrial hygiene journals. Additional reports of take-home incidents were solicited from federal and State health, labor, and environmental agencies. As the authors of the Report acknowledge, there are substantial limitations in the available literature. An important limitation is that U.S. reporting systems for sentinel exposures and health outcomes are limited to lead and pesticides. Moreover, the Report notes that community clinicians may not recognize diseases that result from take-home exposures because they fail to obtain relevant information on family members' occupations. Systematically-obtained data on exposure types and levels for most agents are lacking, even for lead and pesticides which have been the subject of considerable focus. Additionally, the Report acknowledged that much of the literature summarized pertains to exposure conditions that occurred during the 1930s–1960s, and, therefore, may have limited relevance to contemporary home and work environments. The Task Force agrees that these limitations exist.

In general, the Task Force found the Report to be a comprehensive review of episodes of toxicity for the agents that fit the criterion of having a clearly recognizable transported exposure route. However, the scope of the problem of take-home exposures seems to be too narrowly defined in some instances. For example, the nuclear industry has documented cases of various radionuclides carried home on workers clothing, shoes, or on other items (e.g., tools) that are brought home from the workplace. The Task Force concluded that there was an inadequate discussion of potential take-home hazards from radioactive substances. Furthermore, the Report does not consider the broader range of exposures to infectious agents that might be transmitted from workers to their family members by means other than from the presence of pathogens on skin or clothing. The Task Force recognizes that this restrictive definition of infectious agent transmission was prescribed by Congress. Nonetheless, the majority of infectious disease risk to workers' family members is likely to result from other routes of exposure. Of specific concern is the possibility of transmission of infectious diseases to family members of health care workers. Potential risks for reproductive system damage and developmental disorders as a consequence of take-home exposures also did not receive adequate consideration.

Assessing the extent of take-home exposures requires the identification and analysis of contamination transport pathways, and methods of measuring the toxic chemicals of interest. A review of the published literature, as

summarized in the NIOSH Report, does not provide specific information describing these pathways or their analysis. Many of the citations are anecdotal, based on outdated industrial practices, or are summaries of foreign experiences that may not be directly applicable to the United States.

**Gaps in Knowledge**

An understanding of the potential burden of impaired health experienced by workers' family members due to take-home exposures has been limited by significant knowledge gaps in: the types, sources, and magnitude of take-home exposures; the size and characteristics of at-risk populations; the types and severity of potentially associated health effects; and the adequacy of exposure control methods. The following section summarizes the Task Force's conclusions on knowledge gaps and recommended approaches for reducing these gaps.

**Types and Levels of Exposure**

Little systematic research has permitted quantification of previously recognized and emerging take-home exposures. Moreover, identification of new, unanticipated hazards is impeded by limitations of existing research methodology. Past episodes of documented health hazards suggest the importance of determining the extent of take-home exposures from recognized toxic agents, such as lead or beryllium. However, no reliable and feasible methods exist to determine how many homes and families are potentially exposed to established toxicants and what exposure levels might exist.

The difficulties of assessing the extent of exposure to previously unrecognized toxicants are even more daunting. Although it might be argued that contemporary workplace hygienic practices should offer adequate protection against excessive take-home exposures in large, well-organized businesses, small businesses often lack financial resources for exposure reduction programs. A further complication is that it is virtually impossible to predict which workplace agents may in the future pose threats to workers' family members' health. The problem of agent identification and quantification undoubtedly has been compounded in recent years as newer materials have been introduced into the workplace. This trend is likely to continue for the foreseeable future.

Identifying sources of exposures (i.e., workplace or ambient environment) is another difficulty that must be addressed in characterizing exposure pathways.

It will clearly not be possible to institute a nationwide surveillance system for all known and suspected take-home toxicants. Instead, focused approaches can be devised that provide sufficient information to support health-related research or exposure remediation interventions. One recommended approach is to institute regional, and where feasible, national exposure sentinel monitoring systems for agents that have a likely potential for home transport and can be measured reliably. Precedent is provided by the Beryllium National Registry. Such a system would require prioritizing agents on the basis of known toxicity and ease of recognition, and targeting surveillance in areas where workplace exposures are relatively common. Take-home pesticide exposures in rural areas may be a useful prototype because there exist methods for in-home exposure measurement and exposure pathway analyses.

Determining exposures to agents that are not obvious take-home hazards might require input from community health practitioners who should be encouraged to obtain more and better information on the occupational history of family members, at least for current employment. Periodic collection and analysis of data relating disease occurrence to family members' occupations might reveal previously unrecognized associations that warrant further examination.

There are also important knowledge gaps related to defining the populations at risk for take-home toxic exposures, and, ultimately, health hazards. The potentially exposed population includes all household members of workers capable of transporting contaminants into the home, residents of farms, and residents of homes that function as cottage industry workplaces. Exposed household members frequently are children, the elderly, pregnant women, and the ill or disabled. Family members exposed to take-home agents may in some instances have an increased level of vulnerability compared to individuals exposed in an occupational setting. Household members may differ from workers physiologically (e.g., age and health status), behaviorally (e.g., hand-to-mouth and pica behaviors of young children), and educationally (e.g., worker awareness and use of personal protective equipment). For example, children absorb, distribute, and metabolize some toxicants differently than adults. The elderly also exhibit physiologic differences that may alter susceptibility to toxic substances. Elderly persons who have experienced long-term exposures may also have accumulated substantial body burdens before take-home exposures occur. Additionally, the vulnerability of some workers' household members may be affected by low socioeconomic status, which may lead to problems with access to health care, pre-existing diseases, and compromised nutritional status. Limited access to health care is an important issue because workers of lower socioeconomic status may be more likely to hold jobs in which they are exposed to high levels of toxic substances because of inadequate workplace controls; elevated exposure levels may combine with limited access to health care to increase the risk of adverse health effects among workers and their families.

To characterize the exposed population accurately it will be necessary to generate estimates of the number of workers who encounter specific hazardous substances on the job. Descriptions of household sizes, types, and locations will also be needed. These data are not currently available, but may be crudely estimated for some major agents (e.g., asbestos, lead) from national databases and census reports. However, even these estimates are limited by a lack of specific, quantitative information concerning workplace exposure levels and modes of toxicant transport from the workplace to homes. An additional complication will be introduced as the age distribution and living conditions of the exposed population changes. For example, as the U.S. population ages and health care costs escalate, extended families living in the same home may become more common, and the home may become an increasingly frequent site for health care delivery to chronically ill family members. These changes in the profile of the population-at-risk make it difficult to predict the future magnitude of the problem of home contamination.

**Distinguishing Primary Occupational Health Effects From Secondary Take-Home Exposure Effects**

Workers' household members may exhibit different health effects from those seen in workers, thus making detection difficult and potentially obscuring the link to the workplace. Lead, for example, can impair the child development at low levels of body burden, and exposure to estrogenic compounds has been reported to cause hormone-related effects, such as abnormal breast enlargement in children. Other chemicals brought home from the workplace may cause similar toxic effects. Although there are documented instances of these effects following take-home exposures, the

extent of the problem remains unknown. Additionally, adverse reproductive effects have been associated with exposures to several toxic exposures in worker groups, but effects experienced by family members, including pregnant wives of workers, have not been well characterized. Epidemiologic studies of worker families may be useful in this regard. Improved data sources, such as the inclusion of both parents' occupations on birth certificates, should be considered.

Government-mandated standards for levels of workplace exposure are based on protection of adult workers. Guidelines for worker exposures are not intended to protect individuals who may be more vulnerable due to compromised health or age factors. Thus, workers who themselves may not be affected adversely by work exposures may still transport agents to the home that are capable of affecting others in their household. The characteristics of the home environment dictate that some family members may experience take-home toxic exposures throughout the day, especially for persistent agents that can be readily disbursed in the home environment (e.g., lead). Continuous exposures to these substances, even at low levels, may pose health risks to family members.

**Most Important Health Effects**

The literature summarized in the NIOSH Report to Congress indicates that the clearest instances of health hazards related to take-home exposures are those where the pathways of exposure are established and the health effects are both severe and specific to the exposure. The most obvious examples are asbestos- and beryllium-associated lung diseases and lead poisoning. Knowledge of health effects is based largely on case reports rather than population-based studies; consequently, the true spectrum of health outcomes is essentially unknown. Most of the research literature does not address how take-home exposures contribute to diseases with complex or multi-factorial origins (e.g., cancers or birth defects). Other conditions, such as asthma, skin diseases, and neurological dysfunction, are difficult to relate to take-home exposures because of their generally non-specific etiologies.

The health effects of historically important take-home toxicants, such as lead, pose a continuing threat, but remain difficult to monitor because there is no system for evaluating the extent of the problem. For example, as workplace lead standards are lowered it may be anticipated that take-home exposure concentrations would be diminished concomitantly. However, data from population surveys (e.g., NHANES) of blood lead levels cannot reveal the past contribution of take-home occupational exposures to currently occurring health effects due to the overwhelming influence of ambient exposures on body burden.

**Potential Future Threats to Health From Take-Home Exposures**

Severe episodes of toxicity from known hazards, such as lead or pesticide poisoning, will undoubtedly occur in the future with unpredictable frequency. The contributions of less well-established take-home exposures are much less predictable and deserve more scrutiny. Diseases that are clearly increasing in incidence and prevalence, such as childhood asthma, are logical candidates for future study. Health effects of fundamental importance to reproductive function also require further examination, especially given the established association between certain occupational exposures and altered endocrine function.

The wording of the Workers' Family Protection Act limits take-home exposures to agents that are transmitted either from the workers' clothing or external body surfaces. Thus, chemicals or infectious agents harbored in blood or other internal body compartments were considered outside the purview of the NIOSH review. Although this restriction simplifies the scope of exposure control and remediation strategies, possible health risks of considerable public health importance may be excluded from consideration. Blood-borne infections, occupationally acquired by health care workers and subsequently transmitted to family members, is a clear example of such take-home transmission.

**Exposure Remediation**

Remedial measures to protect workers' families should focus primarily on identifying and preventing the transport of potentially hazardous substances from the workplace. NIOSH's National Occupational Research Agenda (April 1996) lists control technology and personal protective equipment as one of 21 research priorities that can lead to improved worker safety and health. It states that ''recognized safety and health hazards can be managed by a variety of engineering, administrative, and worker protection techniques.'' These same techniques can be applied to prevent the contamination of workers' homes with hazardous substances transported from workplaces. Decontamination procedures should be viewed as necessary only when preventive measures were not taken or were inadequate.

There is little research documenting the overall degree of exposure and the extent to which health effects occur because workers inadvertently carry home hazardous substances from work on their clothes, body, or tools; health effects related to some substances, however, are well recognized because of their uniqueness and clear associations with workplace exposures. For these hazardous substances, a modest investment of resources could prevent transport of the substances to workers' homes, first and foremost by enhanced training efforts to increase awareness of the hazards and acceptance of safe work and material-handling procedures by employees and employers (e.g., changing clothes before going home, showering before going home, separating work areas from living or eating areas, using personal protective equipment). Also effective would be the development and distribution of information and education programs aimed at family members and health care professionals.

Take-home contamination can also be managed by instituting and adhering to engineering controls, such as the proper use of equipment, substitution of safer materials, use of equipment with improved engineering designs when available, or using personal protective equipment to isolate the worker from the hazard. Although various control measures have been used to prevent the adverse health effects of known take-home toxicants in workers' families, limited information exists to assess or predict their effectiveness. The Task Force recommends that, at a minimum, an investigative strategy should include: (1) Development of surveillance programs to document the effectiveness of control measures that are being used, including an assessment of the feasibility and effectiveness of alternative measures; (2) an assessment of the performance of existing protective clothing (i.e., single-use disposable and clothing that can be laundered) as barriers for chemical, biological, thermal, and physical hazards; (3) an assessment of the use and acceptance of protective clothing by workers; (4) research on, and development of, new types of materials for protective clothing and gloves, including evaluation of their performance characteristics; and (5) measures to ensure that protective clothing is designed to fit the growing numbers of minority and female workers, and that such clothing is made available to them.

For many occupations, control measures have not been developed because there is a lack of awareness of the potential health effects of take-home toxicants and the extent to which they occur at home. As these hazards become apparent, the Task Force recommends that sufficient technical and financial resources be applied to evaluate the effectiveness of proposed control measures.

The effectiveness of most decontamination procedures has not been adequately assessed, and is dependent on the hazardous substance(s) involved, the manner in which remediation procedures are followed, and the entity that requires decontamination (e.g., person, clothing, surface). Because the primary source of home contamination is via the worker's clothing, items that come in contact with the worker's garments such as automobile seats, carpeting, furniture, and other porous materials, are most likely to require decontamination. Decontaminating reusable garments using home laundry procedures can create problems with contaminated effluent, as well as incomplete decontamination due to the lack of sophisticated laundry techniques and poor use of cleaning temperatures, mechanical action, and appropriate cleaning agents. Furthermore, laundering garments worn by health care workers in locations other than commercial laundries has the potential to contaminate homes with infectious agents transported from the workplace. In these situations, and where there is worker exposure to non-water soluble contaminants (such as asbestos), disposable, single-use garments is an option.

**Proposed Research Agenda**

In proposing a Research Agenda to address potential health hazards resulting from take-home exposures, the Task Force formulated the following questions: (1) What evidence is there that historically-recognized toxic exposures continue to pose health threats to workers' family members; (2) what are the previously unrecognized hazardous exposures; (3) what adverse health effects among workers' family members can be attributed to take-home exposures; and, (4) are exposure control methods effective? The Task Force commented that any scientific determination of the past and ongoing occurrence of impaired health associated with take-home exposures requires coordinated research among professionals with expertise in occupational and environmental exposure assessment, epidemiology, biostatistics, clinical occupational and environmental medicine, and toxicology.

The Task Force recommends that federal and other governmental agencies sponsor research into the types, levels, and determinants (i.e., sources) of take-home exposures, potential adverse consequences experienced by workers' family members, and exposure remediation and control technology. The Task Force notes that the Research Agenda is not intended to be a mutually exclusive list of individual research programs; rather, the Agenda items are interdependent and should engender research efforts that address more than one of these programs concurrently. The research priorities are listed below:

- Characterization of the extent of home contamination with recognized workplace toxicants, including, but not restricted to: toxic metals (e.g., lead, beryllium), pesticides, and dusts (e.g., asbestos);
- Identification of populations at greatest risk of exposure to known and suspected take-home toxicants;
- Assessment of adverse health effects potentially related to take-home exposures, including considerations of previously established adverse effects and newer or less well-studied associations, such as the consequences of transmitting infectious agents and radioactive substances into the home;
- Identification of previously unrecognized toxic exposures that potentially place workers' family members at risk for health impairment; and,
- Assessment of the effectiveness of take-home exposure prevention and remediation methods, including decontamination procedures.

In proposing this research agenda, the Task Force intentionally avoided prescribing specific topics for and methods of investigation. This was due largely to the absence of adequate contemporary information that would indicate which exposures currently present the greatest hazards to family members. This dearth of information is, in fact, what motivated the research agenda recommendations for characterizing exposure conditions. The Task Force felt that responsibility for defining specific topics and scope of research protocols should reside with federal and other governmental agencies, and with private sector research sponsors, who issue requests for research proposals and make research grant awards. Additionally, the Task Force concluded that research on exposure and health assessments related to take-home exposures deserves full consideration by NIOSH under the Institute's National Occupational Research Agenda (NORA).

**Legal and Policy Considerations**

Existing federal statutes have been applied to take-home contamination in a narrow manner, either because of substance-specific statutory language or restrictive enforcement priorities. For example, the toxic-waste remediation efforts of EPA and ATSDR emphasize large-scale contamination events, usually involving neighborhoods or entire communities. Under the Workers' Family Protection Act, these agencies must emphasize assessment of isolated incidents in which only one or a few workers bring home toxic substances from their workplaces. These incidents, are important to identifying the toxic substances most often involved in take-home contamination, determining the means by which contaminants are effectively removed from the workplace to the home, and estimating the extent to which such contamination represents a much larger problem in a particular workplace or industrial sector. The research approach implemented by ATSDR to document these incidents, as well as the Sentinel Event Notification System for Occupational Risks (SENSOR) developed by the National Institute for Occupational Safety and Health, could be adopted by other federal and State agencies involved in take-home contamination research. The data resulting from this research could then be used by federal and State agencies, including OSHA, to promulgate regulations and standards to prevent take-home contamination. In this regard, attention must be paid to the regulatory authority of the Department of Energy/Nuclear Regulatory Commission, Department of Transportation, and the Coast Guard over specialized industries; the involvement of these agencies in strategy implementation is critical to the protection of the families of workers regulated by these agencies.

Of the non-OSHA federal statutes, only the Asbestos Hazard Emergency Response Act of 1986 explicitly addresses take-home contamination. The remaining statutes, however, contain provisions that could be used to prevent and remediate take-home contamination if the agencies that implement these statutes elect to emphasize this issue in the standards and regulations they promulgate. The Workers' Family Protection Act did not anticipate revisions to the existing statutory authority of the federal agencies that may be involved in take-home contamination issues, and none will be needed if these agencies take

advantage of their existing statutory authority to promulgate and enforce standards and regulations that are responsive to the hazardous conditions identified by the Research Agenda developed by this Task Force. Agency responsiveness to the Agenda, however, depends largely on the means by which participation, coordination, and accountability among the agencies are effected. Revision of agency statutes to authorize specifically the prevention and remediation of take-home contamination, especially through revision of the factors used to establish the prioritization schemes used by EPA and ATSDR, should be considered by Congress only if the agencies find it difficult to respond effectively to the Research Agenda.

**Response From the National Institute for Occupational Safety and Health (NIOSH)**

NIOSH supports the research agenda proposed by the Workers' Family Protection Task Force in this report. The recommended research priorities fit within the framework of the National Occupational Research Agenda (NORA) and particularly its priority area ''Special Populations at Risk.'' This plan, developed by NIOSH and more than 500 public and private partners and stakeholders, includes priorities for addressing allergic and irritant dermatitis; asthma and chronic obstructive pulmonary disease; fertility and pregnancy abnormalities; infectious diseases; control technology and personal protective equipment; and many other areas highlighted by the Task Force for consideration. NIOSH supports the recommendations of the Task Force and welcomes public comment on the proposed research agenda.

Dated: January 30, 1998.

**Linda Rosenstock,**

*Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).*

[FR Doc. 98–2824 Filed 2–4–98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0264]**

### Agency Information Collection Activities; Announcement of OMB Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Medical Devices: Substantial Equivalence 510(k) Summaries and 510(k) Statements Premarket Notification'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 16, 1997 (62 FR 38098), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0281. The approval expires on September 30, 2000.

Dated: January 30, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98–2910 Filed 2–4–98; 8:45 am]

BILLING CODE 4160–01–F

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98D–0004]**

### Guidance for Reviewers on Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document for reviewers entitled ''Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act.'' The guidance is intended to clarify the administrative processes that will be followed in implementing the Food and Drug Administration Modernization Act of 1997 (the FDAMA).

**DATES:** General comments on the agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance document entitled ''Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a guidance document for reviewers entitled ''Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act.'' Section 125 of title I of the FDAMA (Pub. L. 105–115), signed into law by President Clinton on November 21, 1997, repealed section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357). As a result of the repeal of section 507 of the act, which took effect immediately, several of the agency's administrative processes for reviewing and approving antibiotic drug applications must be changed. This guidance document is intended to clarify several of the administrative processes that will be followed in implementing section 125 of the FDAMA.

This guidance document represents the agency's current thinking on the implementation of the repeal of section 507 of the act. 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 submit written comments on the guidance document to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9