

for work for the performance of these task order contracts. The Board may revise or accept the IGCE, the task order, and/or some or all of the ABRWH independent dose reconstruction review of contractor's bids. These contracts will serve to provide technical support consultation to assist the ABRWH in fulfilling its statutory duty to advise the Secretary, HHS, on the scientific validity and quality of dose estimation and reconstruction efforts under EEOICPA. These discussions will include reviews of the technical proposals to determine adequacy of the proposed approach and associated contract cost estimates. The information being discussed will include information of a confidential nature. The ICGEs will include contract cost estimates, the disclosure of which would adversely impact the Governments negotiating position and strategy in regards to these contracts by giving the ABRWH independent dose reconstruction review contractor undue advantage in determining the price associated with its bids. The meeting will be closed to the public in accordance with provisions set forth regarding subject matter considered confidential under the terms of 5 U.S.C. 552b (c)(9)(B), 48 CFR 5.401(b)(1) and (4), and 48 CFR 7.304(D), and the Determination of the Director of the Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Public Law 92-463.

A summary of this meeting will be prepared and submitted within 14 days of the close of the meeting.

The agenda is subject to change as priorities dictate.

For Further Information Contact: Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513-533-6825, fax 513/533-6826.

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 CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 28, 2004.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Interim Recommendations for Airborne Exposure Limits for Chemical Warfare Agents H and HD (Sulfur Mustard)

AGENCY: Centers for Disease Control and Prevention (CDC), Public Health Service, Department of Health and Human Services (HHS).

ACTION: Notice of interim recommendations for airborne exposure limits for chemical warfare agents H and HD (sulfur mustard).

SUMMARY: Agents H and HD are stored and are being destroyed by the Department of Defense (DoD). Public Law 99-145 (50 U.S.C. 1521) mandates that the Secretary of Defense carry out the destruction of the United States' stockpile of lethal chemical agents and munitions. Public Law 91-121 and Public Law 91-441 (50 U.S.C. 1512) mandate that, prior to the disposal of any such agent within the United States, the Secretary of Defense implement any precautionary measures recommended by the Secretary of the Department of Health and Human Services (HHS) to protect the public health. This notice provides CDC's interim recommendations for worker and general population airborne exposure limits (AELs) for sulfur mustard. These revised exposure limits replace CDC's previously recommended AELs originally issued in 1988. These limits are being issued as interim criteria pending improved characterization of carcinogenic potential associated with sulfur mustard.

EFFECTIVE DATE: July 1, 2005. An implementation period is necessary to allow the DoD to make program adjustments and allow time for changes to environmental permits as required.

FOR FURTHER INFORMATION CONTACT: Dr. Paul Joe, Chief Medical Officer, Environmental Public Health Readiness Branch, Division of Emergency and Environmental Health Services, National Center for Environmental Health, CDC, 4770 Buford Highway, Mail Stop F-16, Atlanta, Georgia 30341.

SUPPLEMENTARY INFORMATION: On July 22, 2003, CDC published 68 FR 43356, "Proposed Airborne Exposure Limits for Chemical Warfare Agents H, HD, HT (Sulfur Mustard)"¹ seeking public comment. Today's notice discusses major comments received, describes decisions regarding the public comments, and provides interim recommendations. CDC received comments from the U.S. Army, the State of Utah, the State of Colorado, and one employee union.

The comments fell into the following general categories: risk management assumptions used in CDC's deliberations, selection of uncertainty

¹The toxicity data for agent T are inadequate for setting exposure limits. The very low vapor pressure for agent T precludes it as a vapor under normal ambient conditions. For sulfur mustard and T mixtures, air monitoring for sulfur mustard alone should be sufficient under most circumstances to prevent airborne exposure to it.

factors, determination of the cancer potency factor for the mustard AELs, and practical concerns of conducting air monitoring at the lower exposure limits. The key comments potentially impacting CDC's recommendations are summarized and discussed below:

1. One reviewer remarked that the 5-minute ceiling (Ceiling-5M) may require too short of an analytical cycle for use with dual-agent air monitoring instrumentation.

Discussion: The Ceiling-5M was defined to provide a ceiling value for near-real-time (NRT) corrective action that would protect worker health in the short term and meet the long-term goal of keeping the carcinogenicity risk below one in one million. The 8-hour time-weighted average (TWA) exposure limit recommended by CDC in 1988 was implemented by the chemical demilitarization program as a ceiling value, monitored by NRT instruments having a sampling and analysis cycle time of under 5 minutes. CDC's proposal sought to reflect this conservative implementation of the 1988 criteria.

CDC closely examined the various implicit exposure doses, measured in terms of concentration multiplied by time of exposure (Ct), for various potential exposure scenarios. The ceiling-5M was based upon the analytic cycle times used in the stockpile demilitarization program. Longer sampling and analytic cycle times, such as those used in the monitoring programs for chemical agent storage facilities or nonstockpile program, could be considered in a similar manner, that is, by evaluating the effect on the Ct by changing duration of potential exposure with varying instrument cycle times.

CDC examined the implication of applying the ceiling-5M agent concentration with cycle times greater than 5 minutes. Comments received from the Army, indicated that the dual agent monitors use cycle times of up to 10 minutes. Accordingly, CDC reviewed the impact of using 10- to 15-minute cycle times at the same concentration used with the ceiling-5M. Both the short-term and long-term health protection goals were met; that is, the effective dose or Ct associated at this level and duration are still well under the Ct for the acute threshold of effects level (referenced in the July 22, 2003, support document for the proposed sulfur mustard AELs) and the carcinogenicity risk per episode would be well under one in one million.

The above analysis would suggest that a longer analytic cycle time, even up to the 15 minutes, associated with the Army's NRT monitoring definitions, would be acceptable at the

concentration proposed with the ceiling-5M. However, real-world leaks, spills, or other unplanned agent releases do not follow a defined pattern of gradual airborne concentration increase. The first cycle of a monitoring alarm could be at much higher concentrations than the ceiling-5M. Consequently, to limit potential agent exposure durations at higher level exposures, analytic cycle time should be kept as short as practicable.

The final factor considered in CDC's review of this issue is the overall risk management implication of modifying the implied cycle time associated with the ceiling AEL. Clearly, the degree of protectiveness increases as the cycle time decreases, assuming all other quality control criteria remain constant. However, if programmatic delays or extraordinary new personnel protective measures are introduced as interim measures in the pursuit of more ideal monitoring capabilities, overall risk could increase to both workers and the public.

In summary, CDC believes that the proposed ceiling-5M was overly proscriptive and possibly counterproductive. Accordingly, CDC redesignated this AEL as a 15-minute short-term exposure limit (STEL). The concentration value, 0.003 mg/m³, from the ceiling-5M is retained. This STEL is to be monitored with NRT technology using the shortest practicable instrument cycle time. For the maximum 15-minute duration of the STEL, the Ct is 0.045 mg-min/m³.

2. One reviewer remarked that using the proposed general population limit (GPL) for worker protection could result in excessive false-positive situations and attendant disruptions wherever significant interferences might be located.

Discussion: The GPL is a criterion that is set to protect the general public. Community exposure limits are set lower than worker limits to reflect wider variation in human susceptibility than that of the healthy worker population.

CDC premised its proposal to use the new GPL as a worker protection criterion on two basic considerations. First, because the GPL is designed to protect the community, it would also be adequate for a worker population. Second, CDC believed that historic monitoring for the GPL for demilitarization perimeter monitoring similarly could be implemented in worker locations to accommodate longer 12-hour shifts.

As discussed in CDC's proposal, the GPL for sulfur mustard was driven largely by the goal of protecting the public at a cancer risk level of less than

one cancer incidence in a million exposures at the GPL for 3 continuous years, a risk level that is considered to be negligible. Three years was chosen for the duration of the potential exposure at a GPL because it was believed to be the maximum duration of a campaign where sulfur mustard munitions would be handled and processed for destruction on a continuing basis. This assumed exposure scenario is conservative for both the public and workers for a number of reasons:

- No one worker works continuously for 3 years; actual time at work is probably well under one-third of all available hours per year when weekends, holidays, and vacations are considered.

- Demilitarization plant workers, storage site workers, non-stockpile site workers, or others who might reasonably be exposed to chemical agent do not remain stationary at one duty location for extended periods.

- Similarly, the individuals within the general community would not normally be anticipated to stay at one location continuously for 3 years.

- Varying meteorological conditions would preclude constant exposure conditions.

- With the rigorous active demilitarization site monitoring and the ongoing routine storage site inspection program, unplanned releases of chemical agent are unlikely to be sustained for any significant duration.

- CDC assumed exposure at the full GPL in its carcinogenicity evaluation even though detection at this level would result in investigation and remedial action. Typically, risk assessment professionals use some fraction of a "practical quantification limit" or detection level.

The above mitigating factors suggest that long-term exposure scenarios (up to 3 years) used to estimate sulfur mustard carcinogenicity review overstates the true risk. Accordingly, CDC recommends retaining the proposed GPL for perimeter monitoring stations at demilitarization facilities and evaluation of the allowable stack concentrations.

For worker protection against low-level exposure, CDC now recommends a separate 8-hour TWA for a worker protection limit (WPL) rather than applying the GPL as originally proposed. In the earlier proposal for mustard AELs, CDC investigated the development of a WPL using the Environmental Protection Agency (EPA) Categorical Regression (CatReg) method. The value derived from this method is 0.0003 mg/m³. This value is in

reasonably close agreement with the U.S. Army Center for Health Promotion and Preventive Medicine (CHPPM) reference concentration-derived (RfC) WPL of 0.0004 mg/m³ and the Agency for Toxic Substances and Disease Registry (ATSDR) acute inhalation minimum risk level (MRL)² of 0.0007 mg/m³ (1,2). CDC believes that the CHPPM-recommended value for an 8-hour TWA is protective for noncarcinogenic effects and should be implemented for worker protection.

3. The Army noted that, although CDC specified that the proposed AELs were developed for and based upon agent stockpile demilitarization practice, other non-stockpile and storage situations existed to which the AELs would be applied within other Army programs. Illustrations of a number of such situations and some suggested resolutions were provided for CDC's consideration.

Discussion: In CDC's proposal, the use of Ct evaluations was emphasized as an indication of potential acute exposure dose. For potential applications beyond strict stockpile demilitarization, adjustments to implementation of AELs might be warranted on the bases of site-specific or activity-specific conditions. However, any such potential AEL implementation and adjustment for site-specific conditions must ensure that the new monitoring action level protects at the potential exposure dose (Ct) so that the recommended 8-hour WPL is not exceeded. Also, any NRT monitors should not have action levels set above the recommended STEL.

4. Two reviewers commented that CDC's selection of the National Academy of Science (NAS) cancer potency factor (CPF) was inappropriate because the benzo-a-pyrene (BaP) index value used was based upon oral, not inhalation, exposure. They also believed that CDC should use the 30-year exposure assumption described in EPA's risk assessment guidelines.

Discussion: To estimate cancer risk, exposure assumptions and a numeric estimate of the potency of carcinogenicity of a substance are necessary. The reviewers believed that CDC should have used a 30-year duration for such exposure at the lifetime adjusted daily dose. CDC appreciates the general desirability to be

² ATSDR defines an MRL as "an estimate of daily human exposure to a substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified route and duration of exposure." ATSDR also developed an intermediate MRL (continuous exposure for up to 1 year) for sulfur mustard at a value of 0.00002 mg/m³ that is numerically equivalent to the interim GPL recommended herein.

consistent with established guidelines in risk assessment, but EPA has acknowledged in its 1999 Carcinogen Risk Assessment Guidelines (RAG), that "in the face of scientific uncertainty, common sense and reasonable application of assumptions and policies are essential to avoid unrealistic estimates of risk" (3). CDC believes that a 30-year, or even a 10-year, exposure assumption significantly overestimates potential exposures by one or more orders of magnitude. For example, members of the general public are highly unlikely to be continually exposed to sulfur mustard, night and day, for 10 or 30 years. Similarly, atmospheric stability, wind speed, and direction are not fixed for years on end. No agent reduction is assumed for environmental degradations or rainfall that would reduce concentrations. No agent reduction is assumed for low temperature environmental conditions where mustard agent would not significantly volatilize. No agent reduction is assumed for agent dilution beyond the perimeter of a facility. At agent storage sites, GPL readings are taken daily at the facility perimeter. Levels of agent approaching GPL should be detected within days, not years, of occurrence and corrective action would be initiated. Historically, agent releases to the environment have been episodic; no indication exists that continuous, long term low-level agent releases routinely occur.

CDC's examination of the potential cancer risk associated with proposed AELs considered only incremental potential risk. That is, historic risk to workers and the public in the vicinity of stockpile storage facilities was not examined. This was because each site would have to be considered individually regarding amount, nature and age of stored mustard items; local spatial, and meteorologic conditions and their relation to area demographics; and the nature and capabilities of historic storage facility inspection programs. These site-specific factors, coupled with a weak quantification of cancer potency (see discussion below) of sulfur mustard, suggested limited utility in attempting to quantify such potential risk.

The other major criticism received by CDC regarding carcinogenicity analysis pertained to the use of the NAS recommended CPF (2000) based upon sulfur mustard relative potency compared with BaP. The NAS recommendation was predicated upon oral dosage, not inhalation. CDC believed that the other published studies used to support attempts at developing numeric estimates of the

CPF for sulfur mustard seriously lacked merit for this application. Although an averaging estimate (i.e., geometric mean) for all the CPFs developed might provide a reasonable estimate, CDC believes that a mathematic manipulation of questionable numbers in no way ensures that the new number is appropriate. Furthermore, CDC believes that without a reasonable basis to suggest the estimates used in the averaging method bracket the true CPF as applied to humans; CDC should not arbitrarily rely on a number developed in this manner.

CDC agrees with the reviewers that extrapolation between exposure routes is undesirable when examining cancer risk. EPA's 1999 Carcinogen RAG addresses this issue briefly: "In the absence of contrary data, the qualitative default assumption is that, if the agent is absorbed by a route to give an internal dose, it may be carcinogenic by that route" (3). Furthermore, EPA states that, "For screening or hazard ranking, route-to-route extrapolation may be based on assumed quantitative comparability as a default, as long as it is reasonable to assume absorption by compared routes" (3). In light of CDC's reluctance to use CPF averaged numbers as described above, and in the absence of other, better data, CDC recognized that a route-to-route extrapolation was needed if the carcinogenicity risk through inhalation was to be examined and consequently based its analysis upon the NAS-recommended potency value.

CDC believes that the reviewers raise a valid point regarding the use of the indexed value as done in the Federal Register proposal. The reasonableness of the assumption that both exposure routes result in comparable agent absorption is debatable. CDC does not believe strongly that such an assumption is valid; consequently, CDC is open to further examination of this issue. CDC does not believe that the CPF geometric mean offers any demonstrable scientific improvement over the route-to route extrapolation originally used in CDC's proposal. The reviewers recommend that a range of inhalation cancer slope factors be described according to EPA's Carcinogen RAG. CHPPM presented such a range of factors in the "Evaluation of Airborne Exposure Limits for Sulfur Mustard: Occupational and General Population Exposure Criteria," November 2000 and can be referred to by the reader for insight into the variability of postulated risk dependent upon a range the exposure assumptions and CPFs (1). The CHPPM examination is consistent with EPA's guidance. CDC must caution the reader, however, that these numeric

estimates are tenuous. Oak Ridge National Laboratory's 1993 discussion of this issue for sulfur mustard carcinogenicity illustrates CDC's concerns:

"Unfortunately, quantitative human cancer risk estimates are impractical because the experimental data from animal studies have three large uncertainties:

- Only a few experiments were conducted;
- Many were in a mouse strain that exhibited a high genetic susceptibility to spontaneous pulmonary tumors;
- Routes of administration tested and duration of follow-up observations are not comparable to the human exposures of concern." (4)

In 1991, EPA examined cancer risk estimates that cover the range of cancer slope factors presented in the CHPPM document. EPA observed, "Depending on the unknown true shape of the dose-response curve at low doses, actual risks may be anywhere from this upper bound down to zero" (5). Similarly, in the 2003 ATSDR Toxicological Profile for Sulfur Mustard, the inhalation cancer effects discussion states, "* * * in no case was the exposure level or duration quantified, and therefore, these data are inadequate for deriving dose-response relationships" (2).

CDC recommends that a better characterization of an appropriate cancer slope factor needs to be conducted to set exposure limits. CDC is aware of proposed forthcoming animal research by DoD to examine the chronic impact of long-term exposure to sulfur mustard. CDC encourages this research and the examination of results for possible insights and refinement of an estimate of a more accurate CPF.

5. All four reviewers provided opinions regarding the use of uncertainty factors to derive AELs. One reviewer believed that rationale was sufficient to reduce the total uncertainty used by the National Institute for Occupational Safety and Health (NIOSH) to derive the Immediately Dangerous to Life or Health (IDLH) criterion by a factor of three, which would result in an increase to a value of 2.0 mg/m³. Another reviewer wanted to lower the IDLH by a factor of two because of limitations of military studies used to derive the value. Another reviewer believed strongly that the proposed GPL should be reduced by at least an additional factor of 10 to reflect uncertainties not adequately represented by either the CHPPM examination using the RfC method or the CDC examination using the CatReg method. Finally, another reviewer believed that CDC's total uncertainty

factor of 300 used to derive the GPL was appropriate but recommended that the uncertainty factor for intrahuman variation be decreased from 10 to 3 and the data quality factor be increased from 3 to 10. Supporting rationale was provided for all these opinions.

Discussion: Professional judgment is needed in the application of uncertainty factors. As discussed in CDC's original support document, considerable deliberation is ongoing regarding the use of uncertainty factors in risk assessment. No validated or calibrated means exist to precisely quantify total uncertainty used in deriving AELs. This was why CDC considered not only at the RfC, CatReg, and carcinogenicity considerations, but also the risk management aspects of safely managing sulfur mustard agent as associated with the demilitarization program.

The reviewer who recommended the minimal 10-fold decrease in the GPL also believed that AELs should be developed independent of risk management considerations. CDC agrees that ideally developed AELs should be independent of existing risk management conditions. One could argue that CDC should "safe-side" the AELs by using highest uncertainty factors recommended by all reviewers and ignore any recommendations for reduction of uncertainty factors. Except for compounds exhibiting hormesis, this approach always would be theoretically safer than using a number derived using uncertainty factors that are not on the most conservative end of the spectrum of professional judgment.

CDC's mission is to enhance public and worker health protection for people associated with or living near chemical agent demilitarization facilities. CDC believes that real-world risk management must be factored into its deliberations. Otherwise, CDC could increase or extend actual risk in the real world to minimize theoretical or undemonstrated risk. EPA's Carcinogenic RAG noted that, "While it is appropriate to err on the side of protection of health and the

environment in the face of scientific uncertainty, common sense and reasonable application of assumptions and policies are essential to avoid unrealistic estimates of risk" (3,6). Furthermore, CDC/NIOSH policy for potential occupational carcinogens states that " * * * policy will be the development, whenever possible, of quantitative RELs (recommended exposure limits) that are based on human and/or animal data, as well as on the consideration of technological feasibility for controlling workplace exposures to the REL" (emphasis added).

Summary and Recommendations

Although CDC received only 4 sets of comments on the proposed mustard AELs, these reviewers clearly tried diligently to represent their perspectives and concerns. Three sets of comments focused primarily upon the process used to develop the proposed AELs, and the fourth focused primarily on the practical implications of the proposed values. In addition to the solicited comments described above, CDC had the original proposal reviewed by other government and professional health risk assessment personnel. With the exception of one reviewer, the CDC approach to developing AELs in concert with ongoing risk management provisions of the chemical demilitarization program was not questioned.

The examination of the carcinogenicity issue is problematic in that CDC believes that a numeric estimation of a cancer slope factor for mustard is not well supported. The CHPPM review of this issue, through the evaluation of the range of attempts at quantifying upper bound cancer risk from exposure to sulfur mustard, has been referenced herein to provide the reader with that perspective; however, CDC cannot say with confidence that the numeric range of slope factors is likely to provide a reasonable estimate of the true carcinogenic potency of this agent.

Because of the uncertainties discussed above, especially the characterization of cancer potency of sulfur mustard, CDC has decided to issue its recommended AELs as interim values pending better understanding of the CPF for this agent. CDC believes that for noncancer effects, the recommended AELs protect worker and public health.

Regarding the implied carcinogenicity risk, CDC believes that the strong risk management provisions, such as engineering and administrative controls within demilitarization facilities, extensive low-level air monitoring, and the previously discussed mitigating factors, minimize cancer risk at the interim AELs.

In summary, CDC recommends the following:

- Defer recommending a cancer potency factor until better data are available.
- Redesignate the ceiling-5M value as a 15-minute STEL, limited to one occurrence per day; CDC encourages shortest practicable analytic cycle times.
- Apply the U.S. Army CHPPM-derived 8-hour WPL for workplace; retain GPL as proposed for use in protecting the general public.
- Implement the recommended AELs as interim values, to go into effect on July 1, 2005; values to remain interim until better cancer potency characterization is available or research data indicate the need for revision.
- Continue to recommend rigorous risk management analysis and practice as has been associated with the chemical agent demilitarization program practice.
- Given the uncertainty in the risk assessment regarding cancer potency, reduced exposures to sulfur mustard to the lowest practicable level.

Table 1 below contains the numeric values for the interim recommended AELs.

Dated: April 27, 2004.

James D. Seligman,
Associate Director for Program Services,
Centers for Disease Control and Prevention.

TABLE 1.—CDC RECOMMENDED INTERIM AIRBORNE EXPOSURE LIMITS*

[All values expressed as mg/m³ in air with concentration × time [Ct — mg — min/m³] values in parentheses]

Sulfur mustard (H, HD ⁺) criteria	General population limit	Worker population limit	Short-Term exposure limit ‡	Immediately dangerous to life or health §
Exposure Level	0.00002 (0.01)	0.0004 (0.19)	0.003 (≤0.04)	0.7 (≤21).
Averaging Time	12 hours	8 hours	≤15 minutes	≤30 minutes.
Recommended Monitoring Method	Historic §§	Historic §§ or Near-real-time.	Near-real-time	Near-real-time.

* Although CDC does not specifically recommend additional reduction factors for statistical assurance of action at the exposure limit, exposures to sulfur mustard should be minimized given the uncertainties in risk assessment, particularly as related to characterizing carcinogenic potency.

† The toxicity data for agent T is inadequate for setting exposure limits. The very low vapor pressure for agent T precludes it as a vapor hazard under normal ambient conditions. For sulfur mustard and T mixtures, air monitoring for sulfur mustard alone should be sufficient under most circumstances to prevent exposure to T.

‡ To be evaluated with near-real-time instrument using shortest practicable analytic cycle time. No more than one exposure per work-shift.

§ The 30-minute period is not meant to imply that workers should stay in the work environment any longer than necessary; in fact, they should make every effort to exit immediately. IDLH conditions require highly reliable dermal and respiratory protection.

§§ Historic monitoring typically is used for time-weighted average (TWA) monitoring where the sample analyzed represents an extended time period, e.g., 8 or 12 hours. Results are not known until laboratory analysis is completed after the sampling event. AELs using historic monitoring are set at levels at which health effects are not expected to occur for most workers. Exposures above the WPL-8, but below the STEL, likewise are not expected to result in significant health effects unless such exposures occur continuously for long periods.

References

1. U.S. Army. Evaluation of Airborne Exposure Limits for Sulfur Mustard: Occupational and General Population Exposure Criteria—47-EM-3767-00. Aberdeen Proving Ground, MD: U.S. Army Center for Health Promotion and Preventive Medicine, November 2000.
2. U.S. Department of Health and Human Services: Toxicological Profile for Sulfur Mustard (Mustard Gas). Atlanta, GA: Agency for Toxic Substances and Disease Registry, September 2003.
3. U.S. Environmental Protection Agency: Draft Guidelines for Carcinogen Risk Assessment. Washington, DC: U.S. Environmental Protection Agency, July 1999; Publication No. NCEA-F-0644.
4. Nicholson W, Watson A. Risk assessment considerations for sulfur mustard. In: Pechura CM, Rall DP (eds.) Veterans at Risk: The Health Effects of Mustard Gas and Lewisite, Washington, DC: National Academy Press, 1993: 390-8.
5. U.S. Environmental Protection Agency: Upper-Bound Quantitative Cancer Estimate for Populations Adjacent to Sulfur Mustard Incineration Facilities. Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, July 1991, Publication No. EPA/600/8-91/053.
6. U.S. Environmental Protection Agency: Policy for Risk Characterization. Memorandum of Carol M. Browner, Washington, DC: U.S. Environmental Protection Agency, March 21, 1995.

[FR Doc. 04-9946 Filed 4-30-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0185]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the

PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for the animal drug user fee cover sheet.

DATES: Submit written or electronic comments on the collection of information by July 2, 2004.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information

is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Animal Drug User Fee Cover Sheet; FDA Form 3547 (OMB Control Number 0910-0539)—Extension

Under section 740 of the act, as amended by the Animal Drug User Fee Act (ADUFA) (21 U.S.C. 379j-12), FDA has the authority to assess and collect certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. Under the new statutory provisions (section 740(e) of the act, as amended by ADUFA), animal drug applications and supplemental animal drug applications for which the required fee has not been paid are considered incomplete and are not to be accepted for review by the agency. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet, FDA Form 3546, is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made, is appropriately linked to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected, to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.