3. Is a needlestick injury the only reasonable route of exposure for healthcare workers? Please explain.

4. Are the assumptions about the amount of exposure to pertuzumab in a healthcare setting reasonable? Please explain.

5. Is the determination that the amount of exposure to pertuzumab in a healthcare setting does not constitute a hazard for healthcare workers reasonably supported by the available scientific information? Please explain.

6. What alternatives could be considered to this approach for monoclonal antibodies to characterize the potential hazard to workers?

Public and Peer Review Charge for the Reevaluation of Liraglutide on the NIOSH List of Hazardous Drugs

The manufacturer's request to reevaluate the inclusion of liraglutide on the NIOSH List proposed that it does not present a potential hazard to healthcare worker exposures because the properties of the drug limit the potential for exposure and therefore adverse health effects from that exposure. To reevaluate this drug, NIOSH reviewed data regarding the hazards and potential for systemic exposure to liraglutide. Based on this reevaluation NIOSH determined that liraglutide does not meet the NIOSH definition of a hazardous drug and recommends that it be removed from the List. Please review the NIOSH reevaluation of liraglutide and consider the following questions.

1. Are the evaluated health effects the appropriate health effects to evaluate? If not, what other health effect(s) should be evaluated and why?

2. Are the assumptions about the potential exposures to liraglutide in a healthcare setting reasonable? Please explain.

3. Is the determination that the amount of exposure to liraglutide in a healthcare setting does not constitute a hazard for healthcare workers reasonably supported by the available scientific information? Please explain.

4. What alternative approaches could be considered to characterize the potential hazard to workers from peptide-based drugs?

5. Is there any additional information that NIOSH should consider in its reevaluation of liraglutide?

References

FDA [2009]. Liraglutide Pharmacology Review. Retrieved from *https://www.accessdata.fda.gov/scripts/cder/daf/.*

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NIOSH [2023]. Procedures for developing the NIOSH list of hazardous drugs in healthcare settings. By Whittaker C, Ovesen JL, MacKenzie BA, Hartley T, Berry KA, Piacentino J. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2023–129. *https://www.cdc.gov/niosh/docs/2023-129/.*

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–0576]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Possession, Use, and Transfer of Select Agents and Toxins (42 CFR part 73)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on August 15, 2023, to obtain comments from the public and affected agencies. CDC did not receive any comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

The CDC will accept all comments for this proposed information collection project. The OMB is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB Control No. 0920–0576, Exp. 1/31/2024)—Revision—Office of Readiness and Response (ORR), Centers for Disease Control and Prevention (CDC)

Background and Brief Description

Subtitle A of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (42 U.S.C. 262a),* requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which may be cited as the *Agricultural Bioterrorism Protection Act of 2002), (7 U.S.C. 8401),* requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins

that have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents and toxins). Accordingly, HHS and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with the Centers for Disease Control and Prevention (CDC) or the Animal and Plant Health Inspection Service (APHIS). See 42 CFR part 73, 7 CFR part 331, and 9 CFR part 121 (the select agent regulations). The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Regulatory Science and Compliance (DRSC) and the APHIS Division of Agricultural Select Agents and Toxins (DASAT) to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. Accordingly, CDC and APHIS have adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

CDC is requesting OMB approval to continue to collect information under the select agent regulations through the use of five forms: (1) Application for Registration for Possession. Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1); (2) Request to Transfer Select Agents or Toxins (APHIS/CDC Form 2); (3) Incident Notification and Reporting (Theft, Loss, or Release) (APHIS/CDC Form 3); (4) Reporting the Identification of a Select Agent or Toxin (APHIS/CDC Form 4); and 5) Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5).

An entity may amend its registration (Section 7(h)(1)) if any changes occur to the information previously submitted to FSAP. When applying for an amendment to a certificate of registration, an entity would complete the relevant portion of the application package (APHIS/CDC Form 1).

Besides the forms listed above, there is no standard form for the following information:

1. An individual or entity may request an exclusion from the requirements of the select agent regulations of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. (Section 3(e) and 4(e)).

2. Annual inspections that are conducted by the entity must be documented. (Section 9(a)(6)).

3. An individual's security risk assessment may be expedited upon written request by a Responsible Official and a showing of good cause. (Section 10(f)).

4. An individual or entity may request approval to perform a ''restricted experiment'' (Section 13).

5. An individual or entity must develop and implement a written security plan, biosafety plan, and incident response plan (Sections 11(a), 12(a), and 14(a)).

6. The Responsible Official must ensure a record of the training for each individual with access to select agents and toxins and each escorted individual is maintained (Section 15(d)).

7. An individual or entity may appeal a denial, revocation, or suspension of registration. (Section 20(a)).

8. An individual may appeal a denial, limitation, or revocation of access approval. (Section 20(b)).

The currently approved annualized burden is 4467. CDC requests OMB approval for an estimated 3504 annual burden hours. The total estimated annualized burden for all data collection was calculated using the 2021 Annual Report of the FSAP available at *https://www.selectagents.gov/resources/publications/annualreport/2021.htm.* Burden has been reduced due to a decrease in the number of respondents. Information will be collected through the FSAP IT system, email, and hard copy mail from respondents. Upon OMB approval, CDC will begin use of the revised forms in January 2024 through January 2027. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Section	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Sections 3 & 4	Request for Exclusions	1	1	1
Sections 5 & 6	Form 4—Report of Identification of a Select Agent or Toxin	917	1	1
Sections 5 & 6	Form 5—Request of Exemption	1	1	1
Section 7	Form 1—Application for Registration	5	1	5
Section 7	Form 1 Sec 6A—Amendment to a Certificate of Registration	144	5	1
Section 9	Documentation of self-inspection	233	1	1
Section 10	Request for Expedited Review	1	1	30/60
Section 11	Security Plan	233	1	1
Section 12	Biosafety Plan	233	1	1
Section 13	Request Regarding a Restricted Experiment	3	1	2
Section 14	Incident Response Plan	233	1	1
Section 15	Training	233	1	1
Section 16	Form 2—Request to Transfer Select Agents and Toxins	229	1	1.5
Section 17	Records	233	1	30/60
Section 19	Form 3—Notification of Theft, Loss, or Release	185	1	1
Section 20	Administrative Review	22	1	1

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