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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC–2020–0046, NIOSH–233–C]

Request for Public Comment on NIOSH Initial Recommendations To Change the Status of Liraglutide and Pertuzumab on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings

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

ACTION: Request for comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (HHS), requests public comment on two draft reevaluations with initial recommendations to change the status of two drugs, liraglutide and pertuzumab, on the NIOSH List of Antineoplastics and Other Hazardous Drugs in Healthcare Settings (List). The reevaluations were developed based on the process described in the NIOSH Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings. Based on the reevaluations, the NIOSH initial recommendations are to remove liraglutide and pertuzumab from the List.

DATES: Electronic or written comments must be received by February 15, 2024.

ADDRESSES: You may submit comments, identified by CDC–2020–0046 and docket number NIOSH–233–C, by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC–2020–0046; NIOSH–233–C). All relevant comments, including any personal information provided, will be posted without change to *https://www.regulations.gov.* Do not submit comments by email. CDC does not accept comments by email. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: R. Todd Niemeier, Ph.D., National Institute for Occupational Safety and Health, MS–C15, 1090 Tusculum Avenue, Cincinnati, OH 45226. Telephone: (513) 533–8166.

SUPPLEMENTARY INFORMATION: NIOSH seeks public comments on its reevaluations with initial recommendations to change the status of two drugs, pertuzumab and liraglutide, on the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings (the List). The NIOSH reevaluations were conducted based on the process described in the NIOSH Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings, available at *https://www.cdc.gov/niosh/docs/2016-161/.*

NIOSH reevaluated the placement of pertuzumab on the NIOSH List in response to a request for reevaluation from the manufacturer. Based on this reevaluation, the initial NIOSH recommendation is to remove pertuzumab from the NIOSH List. In its reevaluation NIOSH determined that, due to the intrinsic molecular properties of pertuzumab and the nature of the specific hazard posed by exposure to pertuzumab, it is not likely to pose a hazard to workers in healthcare settings. The potential adverse health effect relevant to pertuzumab occupational exposure is the increased potential for fetal developmental abnormalities due to oligohydramnios during pregnancy [FDA 2012]. However, the development of oligohydramnios during pregnancy is reversible and would require repeated exposures to pertuzumab that are high enough to cause oligohydramnios through the relevant period of development. Pertuzumab has limited dermal, oral, and inhalation bioavailability due to its intrinsic molecular properties. Repeated unintended exposures resulting from needlestick injuries at levels high enough to result in sustained oligohydramnios is unlikely. For these reasons, pertuzumab is not expected to pose a hazard to workers in healthcare workplaces.

NIOSH reevaluated the placement of liraglutide on the NIOSH List in response to a request for reevaluation from the manufacturer. Based on this reevaluation, the initial NIOSH recommendation is to remove liraglutide from the NIOSH List. In its reevaluation NIOSH determined that, due to the intrinsic molecular properties of liraglutide and the nature of the specific hazard posed by exposure to liraglutide, it is not likely to pose a hazard to workers in healthcare settings. In animal studies liraglutide was reported to cause C-cell specific thyroid tumors [FDA 2009]. This carcinogenic effect was due to mitogenic activity, and the progression required continued liraglutide exposure. The relevance of C-cell specific thyroid tumor formation in response to liraglutide exposure to humans is unknown but cannot be ruled out. Potential fetal developmental abnormalities are also seen in some animal studies, and there may be risk to the fetus in pregnant patients. However, the intrinsic molecular properties of the liraglutide peptide greatly decrease dermal, oral, and inhalation bioavailability, and the hazards related to liraglutide exposure would require repeated needlestick injuries. Systemic exposures in workplaces are not likely to reach levels required for the potential adverse effects to pose a hazard.

In addition to providing the opportunity for public comment, NIOSH is conducting external peer review of its reevaluations. NIOSH has completed the peer review of pertuzumab and will conduct the peer review of liraglutide concurrently with the public review. The charges to the public and peer reviewers are provided below.

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

The manufacturer's request to reevaluate the inclusion of pertuzumab on the NIOSH List proposed that pertuzumab 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. NIOSH developed a scenario for worker exposure to pertuzumab to evaluate this proposal. Based on this scenario NIOSH determined that pertuzumab 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 pertuzumab and consider the following questions.

1. Is this an appropriate method for evaluating the potential for exposure to pertuzumab?

2. Is oligohydramnios the best health effect to evaluate? If not, what other health effect(s) should be evaluated and why?

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/.*

FDA [2012]. US Food and Drug Administration Pharmacology Review of Perjeta. Retrieved from *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/125409Orig1s000PharmR.pdf*

NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. 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 Number 2016–161. *https://www.cdc.gov/niosh/docs/2016-161/*

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