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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/](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

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