TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
Q. Software/Informatics		
13–129	Software and systems engineering—Software testing—Part 1: General concepts	ISO/IEC/IEEE 29119–1 Second edition 2022–01.
13–130	Medical devices and medical systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2–1: Particular requirements for forensic data logging.	ANSI/AAMI 2700–2–1:2022.
13–131	Standard for medical device security—Security risk management for device manufacturers.	ANSI/AAMI SW96:2023.
R. Sterility		
14–597	Water Quality for Processing Medical Devices	ANSI/AAMI ST108:2023.
S. Tissue Engineering		
No new entries at this time.		

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to *CDRHStandardsStaff@fda.hhs.gov*. To be considered, such recommendations should contain, at a minimum, the information available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process*.

Dated: February 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04376 Filed 2–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1051]

Clinical Pharmacology Considerations for Antibody-Drug Conjugates; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates,'' which provides recommendations for the development of antibody-drug conjugates (ADCs). Specifically, this guidance addresses the FDA's current thinking regarding clinical pharmacology considerations and recommendations for ADC development programs, including bioanalytical methods, dose selection and adjustment, dose- and exposure-response analysis, intrinsic factors, QTc assessments, immunogenicity, and drug-drug interactions (DDIs) for ADCs with a cytotoxic small-molecule drug or payload. Currently, there are no final FDA guidances outlining the clinical pharmacology considerations for ADCs. This guidance finalizes the draft guidance of the same title issued on February 8, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on March 1, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as

well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–1051 for ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Rajanikanth Madabushi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 301–796–1537, *Rajanikanth.Madabushi@fda.hhs.gov;* or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301 Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates.'' An ADC is a type of therapeutic biologic product that is composed of a small-molecule component and an antibody component conjugated together by a chemical linker. An antibody or antibody fragment carrier is selected or engineered against a specific antigen of interest present on the target, which is ideally unique to the disease state being treated (*e.g.,* a tumor-specific antigen). In general, when the antibody or antibody fragment binds to its target antigen, the ADC is internalized through physiological mechanisms (*e.g.,* endocytosis), at which point the small-molecule drug or payload moiety is released either upon exposure to the low pH of the lysosome or by degradation of the antibody/linker by lysosomal enzymes. The released small-molecule drug then exerts its effect in the targeted cell (*e.g.,* the cells expressing the specific antigen of interest) while ideally minimizing the effect on healthy cells (*e.g.,* cells that do not express the specific antigen of interest).

ADCs combine the selectivity of an antibody or antibody fragment with the potency of a small molecule. Therefore, development of ADCs requires careful consideration of the differences between the clinical pharmacology of the antibody or antibody fragment and the small molecule. This guidance addresses FDA's current thinking regarding clinical pharmacology considerations and recommendations for ADC development programs, including bioanalytical methods, dose selection and adjustment, dose- and exposure-response analysis, intrinsic factors, QTc assessments, immunogenicity, and DDIs.

This guidance finalizes the draft guidance of the same title issued on February 8, 2022 (87 FR 7184). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) updates to guidance terminology to provide clarity, (2) additional FDA guidance references included in support of existing guidance text, and (3) additional considerations provided for ADC dosing strategies. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Clinical Pharmacology Considerations for Antibody-Drug Conjugates.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for submission of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for submission of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for submission of biologic license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 201.56 and 201.57 pertaining to the content and format requirements of labeling for prescription drug products and biological products have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 211

pertaining to current good manufacturing practice requirements have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 58 pertaining to good laboratory practice for nonclinical laboratory studies have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: February 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–04375 Filed 2–29–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Wednesday, March 20, 2024 from 11:00 a.m. until 4:30 p.m., and Thursday, March 21, 2024, from 11:00 a.m. until 4:00 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP website as this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted at least one week prior to the meeting at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination. The SACHRP meeting will open to the public at 11:00 a.m., on Wednesday, March 20, 2023, followed by opening remarks from Julie Kaneshiro, Acting Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with a discussion of the draft recommendation, Ethical and Regulatory Considerations for the Inclusion of LGBTQI+ Populations in HHS Human Subjects Research. This topic is a continuation of the discussion and speaker panel presented at the October 2023 SACHRP. This will be followed by discussion of Considerations for Uninformative Research. The first day will adjourn at approximately 4:30 p.m. The second day of the meeting, March 21st, will begin at 11:00 with a discussion of Interpretation of the Best-interests Standard for the Retention of Subjects in Human Subjects Research that Has Been Halted or Suspended. Other topics may be added; for the full and updated meeting agenda, see *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.* The meeting will adjourn by 4:00 p.m., March 21, 2024.

Time will be allotted for public comment on both days of the meeting. The public may submit written public comment in advance to *SACHRP@hhs.gov* no later than midnight March 14th, 2023, ET. Written comments will be shared with SACHRP members and may read aloud during the meeting. Comments which are read aloud are limited to three minutes each. Public comment must be relevant to topics being addressed by the SACHRP.

Dated: February 23, 2024.

Julia G. Gorey,

Executive Director, SACHRP, Office for Human Research Protections.

[FR Doc. 2024–04343 Filed 2–29–24; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this licensing opportunity should be directed to: Andrew Burke Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, email: *burkear@mail.nih.gov* or phone: (240) 276–5484.

SUPPLEMENTARY INFORMATION:

NIH Reference Number: E–251–2023–0.

Title: T Cell Receptors Targeting EGFR L858R mutation on HLA–A*11:01 + Tumors.

Tumor-specific mutated proteins can create neoepitopes, mutation-derived antigens that distinguish tumor cells from healthy cells, which are attractive targets for adoptive cell therapies. However, the process of precisely identifying the neoepitopes to target is complex and challenging. One method to identify such neoepitopes is Mass Spectrometry (MS) when used in conjunction with elution of peptides bound to a specific Human Leukocyte Antigen (HLA) allele. Using MS in this