FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

May 4, 2026

Via Email

Xin He, Ph.D.
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Dear Dr. He and Mr. Ruch:

Thank you for your inquiry submitted under the Information Quality Act (IQA). This letter is in response to your Request for Correction (RFC) (referred to as "Demand for Correction" by the requestor), dated August 7, 2025, and assigned RFC #84 for tracking purposes, that was submitted to the U.S. Food and Drug Administration (FDA) pursuant to the Information Quality Act (IQA) of 2000[1], the Office of Management and Budget (OMB) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies (OMB Guidelines)[2], and the Department of Health and Human Services Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public (HHS Guidelines)[3]. In the RFC, PEER (on its own and on behalf of Xin He, Ph.D.) seeks the removal of the Low-contrast Detectability Test for Assessing Advanced Nonlinear CT Image Reconstruction and Denoising Methods (LCD-CT tool)[4] from the FDA Catalog of Regulatory Science Tools to Help Assess New

[1] Pub. L. No. 106-554, § 515, Appendix C, 114 STAT. 2763A-153.
[2] Office of Management and Budget (OMB) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, Republication, 67 Fed. Reg. 8452 (Feb. 22, 2002).
[3] HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public | ASPE available at https://aspe.hhs.gov/hhs-guidelines-ensuring-maximizing-disseminated-information.
[4] *See* LCD-CT: Low-contrast Detectability (LCD) Test for Assessing Advanced Nonlinear CT Image Reconstruction and Denoising Methods | Center for Devices and Radiological Health available at https://cdrh-rst.fda.gov/lcd-ct-low-contrast-detectability-lcd-test-assessing-advanced-nonlinear-ct-image-reconstruction-and.

Medical Devices (FDA RST Catalog)[5] and additional related actions.[6]

Your RFC is based on your assertion that "the LCD-CT tool does not meet the Information Quality Act's standards for integrity and utility."[7] You request that FDA take the following actions:

- Remove LCD-CT from the Catalog;
- Publicly acknowledge that the tool is not "structured for falsifiability of hypotheses";
- Consider recalling devices related to this complaint or justifying why such devices should not be recalled;
- Review all diagnostic imaging tools for falsifiability and publish results;
- Conduct an internal seminar examining systemic failures evidenced by this case;
- Log a 2018 adverse event into the FDA's Manufacturer and User Facility Device Experience (MAUDE) database; and
- Disclose dispute resolution documents involving Dr. Xin He's concerns related to the inclusion of the LCD-CT tool in the FDA RST Catalog to the public.[8]

Your RFC contains generalized assertions regarding FDA's alleged failure to meet the IQA's integrity and utility standards as they relate to the inclusion of the LCD-CT tool in the FDA RST Catalog.[9] The RFC process is intended for challenging specific information disseminated by the agency that needs to be corrected to comply with agency and OMB guidelines. The RFC contains a number of requests that lack a clear link to the IQA correction process and the guidelines issued pursuant to the IQA. Given the lack of connection between the requests and the IQA and related guidelines, the nature of your RFC and most requested actions are outside of the scope of the RFC process. These requested actions include publication of new disclaimers and studies, recall of devices, internal seminars, adverse event logging, and release of internal dispute documentation. Because these are out of scope, FDA will not respond to these requests. Herein, we will only respond to the request for removal of the LCD-CT tool from the FDA RST Catalog.

The FDA Guidelines[10] outline administrative mechanisms for FDA's pre-dissemination review of information products and describe mechanisms to enable affected persons to seek and obtain corrections from FDA regarding disseminated information that they believe does not comply with the FDA Guidelines, HHS Guidelines, or OMB Guidelines. FDA is committed to applying these guidelines, including each of the updates outlined in the OMB Information

[5] *See* Regulatory Science Tools Catalog | Center for Devices and Radiological Health available at https://cdrh-rst.fda.gov/.
[6] Letter from Public Employees for Environmental Responsibility (PEER) to Office of the Ombudsman, Food and Drug Administration (Aug. 7, 2025) [hereinafter "PEER letter"].
[7] PEER letter at 13.
[8] *Id.*
[9] *Id.*
[10] *See* HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public | ASPE, Part II: HHS Agency Responsibilities and Guidelines, Section F. Food and Drug Administration.

Quality Guidelines and Memorandum M-19-15[11]. The RFC process under the FDA Guidelines is intended to provide a mechanism to correct errors where the disseminated product does not meet information quality standards.

The FDA RST Catalog provides a resource based on peer-reviewed literature to assist the development and assessment of emerging medical technologies where standards and qualified Medical Device Development Tools (MDDTs) do not yet exist. These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed and plans to expand as new tools become available.[12] To that end, FDA published the LCD-CT software toolkit, *i.e.,* the LCD-CT tool, as a regulatory science tool in the FDA RST Catalog on Sept. 24, 2023.[13] A benefit of including the LCD-CT tool in the FDA RST Catalog is that it provides an open source code for a peer-reviewed RST to manufacturers that can choose to utilize and refine it for their desired context of use.

RSTs are voluntary tools that developers may or may not choose to use. If a developer chooses to use an RST, the developer must assess whether it is fit-for-purpose as part of the development, validation, or labeling process. The FDA RST Catalog is an optional aid, and inclusion of the LCD-CT tool provides transparency and saves manufacturers without in-house methods from having to develop such methods on their own. Thus, we find that the inclusion of the LCD-CT tool in the FDA RST Catalog meets the IQA's utility standard[14], *i.e.*, it is useful information to its intended users (CT device developers, CT image reconstruction developers, and image denoising and processing software developers). FDA identifies the LCD-CT tool's intended users on its website, along with the testing performed to ensure that the tool functions as designed, the limitations of the tool, and supporting documentation and references, including peer-reviewed journal articles.[15] [16]

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[11] Office of Management and Budget, Executive Office of the President, OMB M-19-15, Memorandum for the Heads of Executive Departments and Agencies: Improving Implementation of the Information Quality Act (April 24, 2019) available at: https://www.whitehouse.gov/wp-content/uploads/2019/04/M-19-15.pdf.

[12] Regulatory Science Tools Catalog | Center for Devices and Radiological Health.

[13] LCD-CT: Low-contrast Detectability (LCD) Test for Assessing Advanced Nonlinear CT Image Reconstruction and Denoising Methods | Center for Devices and Radiological Health.

[14] *See* 67 Fed. Reg. at 8459, paragraph V.2.; HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public | ASPE, Part I: HHS Overview, D. Framework for HHS Guidelines, 4. Overview of HHS Information Dissemination and Quality Assurance, d. Overview of Quality Assurance Policies and Practices; *id.* at Part II: HHS Agency Responsibilities and Guidelines, Section F. Food and Drug Administration, V. Agency Quality Assurance Policies, Standards, and Processes, A. Utility.

[15] LCD-CT: Low-contrast Detectability (LCD) Test for Assessing Advanced Nonlinear CT Image Reconstruction and Denoising Methods | Center for Devices and Radiological Health.

[16] In regard to your argument in the RFC about integrity, integrity under the OMB Guidelines "refers to the security of information—protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification." 67 Fed. Reg. at 8460, paragraph V.4. Because you have not made any specific allegation, nor are we aware, that the information about the LCD-CT tool in the FDA RST Catalog is unsecure, subject to unauthorized access or revision, or otherwise compromised, we conclude your assertion about integrity under the IQA is without merit.

Information generated from use of RSTs is not the only data or information provided to FDA in support of a marketing submission. Again, as FDA explains and cautions on its website[17] regarding the FDA RST Catalog:

> *These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed. If you are considering using a tool from this catalog in your marketing submissions, note that these tools have not been qualified as Medical Device Development Tools and the FDA has not evaluated the suitability of these tools within any specific context of use. You may request feedback or meetings for medical device submissions as part of the Q-Submission Program.*

FDA reviews CT devices, including their associated reconstruction algorithms. In doing so, FDA routinely makes determinations regarding whether the methods used by the manufacturer to evaluate CT devices, including RSTs, constitute valid scientific evidence acceptable to support the Agency's authorization decision. FDA considers a variety of factors, including the device-specific indications or claims, context of use of the evaluation method, and whether the methods are scientifically valid. The LCD-CT tool alone is insufficient to make patient or disease specific claims. If used, the information from the LCD-CT tool is just one aspect, among many others, that FDA review teams will consider. Limitations of the LCD-CT tool are well understood by FDA review teams and have been identified in the FDA RST Catalog for device developers to take into consideration.

FDA recognizes that the requestor holds a differing scientific opinion regarding the Channelized Hotelling Observer (or CHO) and its incorporation into the LCD-CT tool. Model observers, such as CHO, are considered scientifically valid and have been used by the scientific community for assessing image quality for over two decades.[18]

Finally, your RFC inappropriately conflates research, which should be structured for falsifiability of hypotheses, with a tool designed to be used in that research. Falsifiability can be defined as the characteristic of a hypothesis to be stated in a way that it can be proven false by empirical evidence. Empirical evidence is most accurate and trustworthy when data is gathered using validated methods. It therefore follows that a method or tool (and its development) is not intrinsically falsifiable. Instead, a validated method, such as the LCD-CT

[17] Regulatory Science Tools Catalog | Center for Devices and Radiological Health.

[18] Racine D, Ba AH, Ott JG, Bochud FO, Verdun FR. Objective assessment of low contrast detectability in computed tomography with Channelized Hotelling Observer. Phys Med. 2016 Jan;32(1):76-83. doi: 10.1016/j.ejmp.2015.09.011. Epub 2015 Oct 26. PMID: 26515665; Gallas, BD, Barrett, HH. Validating the use of channels to estimate the ideal linear observer. J Opt Soc Am A Opt Image Sci Vis. 2003 Sep;20(9):1725–38. doi:10.1364/josaa.20.001725. PMID: 12968645; Barrett HH, Yao J, Rolland JP, Myers KJ. Model observers for assessment of image quality. Proc Natl Acad Sci U S A. 1993 Nov 1;90(21):9758-65. doi: 10.1073/pnas.90.21.9758. PMID: 8234311; PMCID: PMC47653; Zhang Y, Leng S, Yu L, Carter RE, McCollough CH. Correlation between human and model observer performance for discrimination task in CT. Phys Med Biol. 2014 Jul 7;59(13):3389-404. doi: 10.1088/0031-9155/59/13/3389. Epub 2014 May 30. PMID: 24875060; PMCID: PMC4057982.

tool, can be used to gather empirical evidence to objectively assess/test a scientific hypothesis and demonstrate whether that hypothesis is false. In other words, it is the hypothesis that needs to be falsified and not the methods used to assess the falsifiability.

For the reasons stated above, we respectfully decline your Request for Correction and decline to take the actions you requested. Accordingly, we are denying your request that FDA remove the LCD-CT tool from the FDA RST Catalog.

Thank you for your interest in the quality of information disseminated by FDA. If you do not agree with FDA's decision about your complaint, you may send a request for reconsideration within 30 days of receipt of our decision. You may use any of the Procedures for Submitting Complaints described in the FDA specific guidelines contained in the HHS Information Quality Guidelines available at: https://aspe.hhs.gov/hhs-guidelines-ensuring-maximizing-disseminated-information. A request for reconsideration should state the reasons why you believe the response is inadequate, should be designated as an "Information Quality Appeal," and sent to the following address:

Food and Drug Administration
Office of Ombudsman
10903 New Hampshire Avenue
WO Building 1, Room 4208
Silver Spring, MD 29993
Email: Ombuds@OC.FDA.gov

Sincerely,

ELLEN J. FLANNERY -S

Digitally signed by ELLEN J. FLANNERY -S
Date: 2026.05.04 11:41:54 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Center for Devices and Radiological Health

cc: Laurie Lenkel