MOU Number 225-19-030

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE DEPARTMENT OF VETERANS AFFAIRS (VA)
AND
THE FOOD AND DRUG ADMINISTRATION (FDA)

1. **PURPOSE:** This memorandum of understanding (MOU) formalizes an understanding between the Department of Veterans Affairs (VA) and the Food and Drug Administration (FDA), hereafter referred to as the "Partners," whereby FDA provides quality assurance support for the VA's centrally managed contracts for human drugs, biologics, , and combination products (hereinafter referred to as medical products), as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act (PHS Act). [1]

2. **APPLICABLE LAW AND REGULATIONS:**
    1. The Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 301 et seq.
    2. 21 U.S.C. § 331(j), Prohibited Acts.
    3. 21 U.S.C. § 360j(c), Trade Secrets.
    4. 21 CFR Part 20, Public Information.
    5. 21 CFR Part 21, Protection of Privacy.
    6. 45 CFR Part 5, Freedom of Information Regulations.
    7. Public Health Service Act (PHS Act), 42 U.S.C. § 262.
    8. 42 U.S.C. § 241(d), Protection of privacy of individuals who are research subjects.
    9. The Freedom of Information Act (FOIA), 5 U.S.C. § 552.
    10. The Privacy Act of 1974 (Privacy Act), 5 U.S.C. § 552a.
    11. 18 U.S.C. § 1905, Trade Secrets Act.
    12. 45 CFR Part 5b, HHS Disclosure Privacy Act Regulations.
    13. 21 CFR Part 4, Regulation of Combination Products
    14. 21 CFR Part 210, Current Good Manufacturing Practice in Manufacturing Processing, Packing, or Holding of Drugs; General.

[1] For the purposes of this MOU, the term "medical products" does not include compounded human drugs subject to sections 503A & 503B of the FD&C Act, or to repackaged human drug products made by state-licensed pharmacies, Federal facilities or outsourcing facilities registered under Section 503B of the FD&C Act, in accordance with guidance entitled "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." (see https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf).

15. 21 CFR Part 211, Current Good Manufacturing Practice of Finished Pharmaceuticals.
16. 21 CFR Part 212, Current Good Manufacturing Practice for Positron Emission Tomography Drugs
17. 21 CFR Part 600, Biological Products: General
18. 21 CFR Part 606, Current Good Manufacturing Practice for Blood and Blood Components

3. BACKGROUND: The Office of Management and Budget (OMB) and the General Accountability Office (formerly the General Accounting Office) (GAO) completed separate studies in late 1973 and early 1974 of the Federal procurement of medical and non-perishable subsistence supplies. OMB and GAO recommended that FDA be the Agency responsible for quality assurance of all medical products procured by Federal agencies. In June 1974, the director of OMB requested that the Department of Health, Education, and Welfare (HEW), now known as Health and Human Services (HHS), take the lead in developing an executive branch plan for a government-wide quality assurance program (GWQAP) for medical products. FDA was responsible for developing and implementing the plan.

Because of the diversity of medical products procured by the Federal government, FDA first developed a quality assurance program covering drugs and biologics. On June 19, 1975, FDA and VA signed an agreement in which FDA assumed responsibility for providing quality assurance for all drugs, biologics, chemicals, and reagents that the VA procures, stores, and distributes, including its Federal Supply Schedule.

This MOU updates and supersedes the previous MOU between the Partners dated June 19, 1975, by

- Updating the scope of the MOU by excluding chemicals and reagents and including devices and combination products,
- adding references to applicable statutes and regulations (Section 2),
- adding data sharing guidelines related to non-public information (Section 5), and
- updating the Partners' responsibilities (Section 4) and points of contact (Section 7).

4. RESPONSIBILITIES:

a. The VA agrees to:

1) Furnish FDA all relevant information needed by FDA concerning the firm and the products involved, when requesting an evaluation of a firm's capability to supply a quality medical product.

2) Inform FDA immediately whenever any information is received by the VA which may impact adversely on the quality assurance of any firm or medical product subject to VA procurement or considered for VA procurement.

3) Furnish justification when requesting that FDA conduct an on-site inspection of a firm, analysis of a product, or other work the VA believes necessary to provide quality assurance of the product(s).

4) Participate fully in FDA's safety information and adverse event reporting program, in addition to conducting its own internal reporting system. Reports may be made via https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program.

5) Submit samples and request analysis in accordance with procedures FDA establishes.

b. FDA agrees to:

1) Perform inspections for compliance with current good manufacturing practice (CGMP)regulations for human drug, biologic, medical device, tissues, and combination product manufacturers that are registered and listed with the Agency, upon request by the VA and as appropriate when past inspection history or other information is unavailable for FDA to attest to a firm's compliance with CGMP regulations and assure product quality.[2]

2) Use the standards set forth under 21 CFR Parts 4, 210, 211, 212, 600, 606, 820 and 1271 to assess the manufacturing, processing, packing, or holdings of medical products procured by the VA, as appropriate.

5. DATA SHARING GUIDELINES:

Both Partners recognize that information exchanged that contains any of the following types of information must be protected from unauthorized use and disclosure: (1) confidential commercial information, such as the information that would be protected from public disclosure pursuant to Exemption 4 of the FOIA; (2) personal privacy information, such as the information that would be protected from public disclosure pursuant to Exemption 6 or 7(C) of the FOIA; or (3) information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. § 1905), the Privacy Act (5 U.S.C. § 552a), other FOIA exemptions not mentioned above (5 U.S.C. § 552(b) and the FD&C Act (21 U.S.C. § 301 et seq.)). Pursuant to FD&C Acts sections 301(j) (21 U.S.C. § 331(j)) and 520(c) (21 U.S.C. § 360j(c)), FDA will not reveal to the VA any method or process which is entitled to protection as a trade secret, and will not disclose to the VA confidential commercial information relating to devices obtained by FDA under sections

[2] In general, FDA bases its attestation of compliance with CGMP, QS, and CGTP regulations on the manufacturer's most recent FDA inspection and other available information. Generally, FDA CGMP and QS regulations are intended to ensure that the manufacturer can manufacture, process, package, and hold a product to ensure that it meets the requirements of the FD&C Act as to safety, identity, strength, quality, and purity. FDA GTP regulations are intended to prevent the introduction, transmission, and spread of communicable diseases by human cells).

513, 514, 515, 516, 518, 519, 520(f), 520(g), or 704 of the FD&C Act (21 U.S.C. 360c, 360d, 360e, 360f, 360h, 360i, 360j(f), 360j(g), 374).

Access to the information shared under this MOU shall be restricted to authorized FDA and VA employees, agents, and officials who require access to perform their official duties in accordance with the uses of information as authorized by this MOU. Such personnel shall be advised of (1) the confidential nature of the information; (2) safeguards required to protect the information, and (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws. Contractors, their subcontractors, and agents requiring access to the information shared under this agreement will be required to sign a business associate agreement by which they will commit to keep the information confidential.

Provisions for sharing non-public information in accordance with applicable statutes and regulations are set out below:

a. Before the sharing Partner provides any non-public information, the Partner will agree in writing, by using the attached model request language (Attachment A1), or a reasonable, mutually agreed upon variation, not to further disclose any shared non-public information without prior written permission from the sharing Partner, unless required by law. All non-public information shared between FDA and the VA shall not be shared with any party unless the VA obtains permission from the FDA before disclosure.

b. If given permission by the FDA, the VA will include a transmittal letter along with any information shared. The transmittal letter will indicate the type of non-public information to be shared. A model transmittal letter is attached (Attachment A2). The shared documents containing non-public information should include the following language: "This document contains non-public information. Do not disclose without permission of [*Insert name of sharing partner*]." Any Partner may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request.

c. The requesting Partner will limit the dissemination of shared non-public information it receives to internal unit offices and/or employees that have been identified in its written request. If the requesting Partner determines that employees other than those identified in the original request have a need to know the requested information, then the requesting Partner will send an update to the information sharing request to the sharing Partner and will wait to receive the sharing Partner's consent before distributing the information to those additional employees. The unit official who signs the information sharing request will be responsible for ensuring that there are no inappropriate recipients of the information.

d. The requesting Partner will promptly notify the contact person or designee of the sharing Partner of any attempt by a third party to obtain shared non-public information, including, but not limited to, a FOIA request, congressional request, judicial order, subpoena, or discovery request.

e. If the requesting Partner receives a FOIA request for shared information, the requesting Partner will: (a) refer the FOIA request to the information-sharing contact person or designee for the sharing Partner to respond directly to the FOIA requester, if the request implicates documents from the sharing Partner in their original form, and notify the FOIA requester of the referral and that a response will issue directly from the sharing Partner; or (b) consult with the sharing Partner about how to respond to the FOIA request through the information-sharing contact person or designee for the sharing Partner, if the request implicates documents authored by the requesting Partner and incorporate information from shared documents. The requesting Partner will not indicate to the FOIA requester whether the sharing Partner has responsive records or releasable records.

f. The Partners will promptly notify each other of any actual or suspected unauthorized disclosure of information under this MOU.

6. ADMINISTRATION:

This MOU represents the broad outline of the Partners' intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to FDA and the VA. All activities undertaken pursuant to the MOU are subject to the availability of personnel, resources, and funds. This MOU does not affect or supersede any existing or future agreements or arrangements among the Partners. This MOU does not create binding, enforceable obligations against any party. This MOU and all associated agreements will be subject to the applicable policies, rules, regulations, and statutes under which FDA and the VA operate.

a. VA and FDA agree to coordinate efforts with respect to supplier visits.

b. VA contracts for medical products will include a provision requiring compliance with the applicable FD&C and PHS Acts and implementing regulations promulgated thereunder. FDA will be responsible for administrative interpretation and enforcement of the FD&C and PHS Acts and implementing regulations promulgated thereunder.

c. VA may authorize FDA to inspect, verifying medical product manufacturers and suppliers on behalf of the VA.

d. FDA and the VA, as necessary, will jointly prepare procedures covering operations that interface.

7. PARTICIPATING ACTIVITY LIAISON OFFICERS:

a. For VA: Chief Consultant, Pharmacy Benefits Management, 1st Avenue – 1 Block North of Cermak Road, Hines, IL 60141.

b. For FDA: Director, Division of Systems Solutions, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20857.

8. EFFECTIVE DATE, MODIFICATION, OR TERMINATION OF MEMORANDUM OF UNDERSTANDING

a. This MOU will become effective upon the date of the final signature by the last Partner and will remain in effect unless terminated as prescribed in paragraph 8(c) below.

b. This MOU embodies the entire understanding between the Partners and will be reviewed every two years to ensure adequacy and currency; however, it may be amended by written mutual consent by the Partners or authorized representatives at any time.

c. This MOU may be unilaterally terminated by either Partner by providing the other Partner with 180 days written notice of intent to terminate. This MOU may also be terminated at any time upon the mutual written agreement of the Partners.

APPROVED AND ACCEPTED FOR THE VETERANS ADMINISTRATION

Jennifer Zacher

Jennifer L. Zacher 146179

Digitally signed by Jennifer L. Zacher 146179
Date: 2020.06.30 08:34:47 -05'00'

Deputy Chief Consultant, PBM for
Department of Veterans Affairs

DATE

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

Erik P. Mettler

Erik P. Mettler -S

Digitally signed by Erik P. Mettler -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300153934, cn=Erik P. Mettler -S
Date: 2020.06.25 09:23:28 -04'00'

Assistant Commissioner for Partnerships and Policy
Food and Drug Administration
DATE

Attachment A1 -- Model Language for Information Sharing Request

MOU No. 225-19-030

Process for Information Sharing

Pursuant to Section 5 of the Memorandum of Understanding (MOU) entered into by the Food and Drug Administration (FDA) and the Department of Veterans Affairs (VA), the partners "may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request." Nothing in the process described below changes Section 5.

If, pursuant to this MOU, staff at FDA or the VA request from the other agency information that may contain non-public information, the request should be made in writing (an informal email is sufficient) and need only identify the subject for which information is requested. Although a more specific description of the information asked for may be helpful, it would not be required for purposes of making a request. However, the following language should be included in the request:

> [Requesting Partner] agrees that it will not further disclose any shared non-public information in any manner without prior written permission or as required by law without prior written notice to the FDA. [Requesting Partner] will act in accordance with the principles and procedures on information sharing set forth in the Memorandum of Understanding (MOU) between FDA and the VA (MOU No. 225-19-030).
>
> [Requesting Partner] will limit dissemination of any shared information to the following [Requesting Partner] offices and/or employees: [Identify office(s) and/or employee(s)]

_____ _____

NAME DATE

Attachment A2 -- Model Transmittal Letter for Information Sharing

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This letter accompanies agency records the [Sharing Partner] is sharing with the [Requesting Partner] in response to the [Requesting Partner]'s request, dated _____. The information/documents provided in response to the [Requesting Partner]'s request include the following: [Describe or identify each piece of document/information provided.] These agency records contain one or more of the following categories of nonpublic information, which include information the further disclosure of which may be prohibited by law.

([Sharing Partner] checks applicable categories below)

____ Trade secret
____ Confidential commercial or financial information
____ Information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy
____ Information contained in records subject to the Privacy Act
____ Information contained in inter-agency or intra-agency memoranda (including information protected by the deliberative process, attorney-client, and/or attorney work product privileges)
____ Records or information compiled for law enforcement purposes; or
____ Information protected for national security reasons; or
____ Other

The shared non-public information may not be disclosed or shared in any manner without the express written consent of the originating agency or as required by law with advance notice to the originating agency. The shared documents containing non-public information are stamped with "This document contains non-public information. Do not disclose without permission of [Sharing Partner]."

[Requesting Partner] shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain such shared non-public information by third parties, including, but not limited to, Freedom of Information Act requests, Congressional requests, judicial orders, subpoenas, discovery requests, and litigation complaints or motions.

[Requesting Partner] has acknowledged that applicable laws and regulations may limit or restrict the disclosure of such information. See, e.g., 5 U.S.C. § 552; 5 U.S.C. § 552a; 18 U.S.C. § 1905; 42 U.S.C. § 241(d); 21 CFR Parts 20 and 21; and 45 CFR Parts 5 and 5b. FDA cannot share trade secret information covered under 21 U.S.C. §§ 331(j) and 360j(c).

[Requesting Partner] has also agreed to act in accordance with the principles and procedures set forth in the Memorandum of Understanding on information sharing between FDA and VA (MOU No. 225-19-030).

_____	_____
NAME	DATE