MEMORANDUM OF UNDERSTANDING

ON

Sustainability of Federal Collaboration on Pharmaceuticals in Drinking Water

BETWEEN THE

U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)
OFFICE OF WATER (OW)

AND THE

U.S. DEPARTMENT OF AGRICULTURE (USDA)
AGRICULTURAL RESEARCH SERVICE (ARS)

AND THE

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
FOOD AND DRUG ADMINISTRATION (FDA)

AND THE

U.S. DEPARTMENT OF INTERIOR (DOI)
U.S. GEOLOGICAL SURVEY (USGS)

I. Purpose

This four-Party Memorandum of Understanding (MOU) establishes a formal mechanism among the US Environmental Protection Agency (EPA/OW), the US Department of Agriculture (USDA/ARS), the US Department of Health and Human Services (HHS/FDA), and the US Department of Interior (DOI/USGS), (collectively the 'Parties'), to improve and sustain federal coordination and collaboration on issues related to pharmaceuticals in drinking water.

This agreement is in response to the Government Accountability Office's (GAO) recommendation made to the Administrator of the EPA in its August 2011 report "Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water."

II. Authorities

This MOU is signed by the USGS pursuant to the Organic Act of 1879, 43 U.S.C. 31 et seq and 43 U.S.C. 36c. This MOU is signed by the EPA pursuant to the Safe Drinking Water Act, Section 1442 and 1457, and the Clean Water Act, Section 104. This MOU is signed by the FDA pursuant to the National Environmental Protection Act, 42 U.S.C. 4321 et seq., the Federal Food, Drug, and Cosmetic Act, Sections 505, 512, and 1003 (21 U.S.C. 355, 360b, and 393), the Public Health Service Act, section 351 (42 U.S.C. 262), and 21 C.F.R. 20.85.

III. Background

Research has detected pharmaceuticals in the nation's drinking water. National and regional studies by the USGS, EPA, and others have detected pharmaceuticals in source water, treated drinking water, and treated wastewater; but the full extent of occurrence is unknown. The concentrations detected for any one pharmaceutical were measured most frequently in parts per trillion. Research has not determined the human health effects of exposure to these concentrations of pharmaceuticals in drinking water but the potential effects of some compounds (e.g., antibiotics and those that interfere with the functioning and development of hormones in humans) have raised concerns among some scientists, the public and policy makers. Additional research is needed that this MOU could help identify and facilitate.

The Safe Drinking Water Act (SDWA) authorizes the EPA to regulate contaminants, including pharmaceuticals, in public drinking water systems if such contaminants may adversely affect human health, among other criteria. Pharmaceuticals may enter drinking water supplies from several pathways, including discharges from wastewater facilities. Another source of pharmaceuticals is agricultural animal production facilities where large numbers of food-producing animals (such as chickens, cattle, and swine) are treated with pharmaceuticals. Pharmaceuticals enter the environment, including sources of drinking water, either directly from waste storage structures as a result of accidents or weather conditions, or through the application of manure and liquid wastes to croplands. A potential pathway is from improper disposal of pharmaceuticals down the drain or toilet and through natural elimination. Some states and local governments as well as the Drug Enforcement Administration have taken actions that could reduce the extent to which pharmaceuticals occur in drinking water. These efforts have primarily been through the implementation of drug take-back programs to encourage proper control and disposal of pharmaceuticals.

EPA faces challenges in obtaining sufficient occurrence and health effects data on pharmaceuticals and other contaminants in drinking water to help support analyses and decisions to identify which, if any, pharmaceuticals should be regulated under SDWA. EPA is collaborating with the FDA, USGS and USDA on research to help obtain such data. To date these efforts have been largely informal. Currently, there is no overall federal interagency plan for research on the effects of pharmaceuticals in drinking water.

In August 2011, the Government Accountability Office(GAO) published a report entitled, "Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water", in which GAO requested that EPA establish a formal mechanism for federal agencies to collaborate and coordinate research on pharmaceuticals and, as appropriate, other contaminants in drinking water that present the greatest public health concern. In response to this request, EPA agreed to establish a workgroup or other formal mechanism with relevant federal agencies. To establish this mechanism, GAO stated that EPA should: 1) define roles and responsibilities (including how the collaborative effort will be led); 2) identify the expertise and other resources (e.g., data, scientific knowledge, tools and other information) each agency can bring to bear on the issue; and 3) develop a process for monitoring, evaluating, and reporting to the public the results of the collaborative research efforts. This MOU provides a mechanism to formalize this process.

IV. Provisions of MOU

A. Establishment of Steering Committee and Workgroup

Collaborative efforts of the Parties will be coordinated by a Steering Committee, consisting of one or two representatives from each Party. The Steering Committee will be jointly responsible for the establishment of an interagency workgroup and for activities such as scheduling and organizing workgroup meetings and/or other events, responding to GAO, and coordinating efforts designed to ensure that the mission of this agreement is advanced. The workgroup will consist of representatives

from the Parties and other federal agencies with responsibilities to address issues related to the occurrence of pharmaceuticals in drinking water and sources of drinking water.

B. Scope of Workgroup Activities

The scope of workgroup activities will encompass a broad range of topics related to pharmaceuticals in water that may be of interest to any subset of agencies on the workgroup. These activities will include, but are not limited to, sharing information on health effects (such as pharmaceutical biological activity and toxicology) and occurrence (sources, fate and transport) that could support scientific analyses and assist in informing policy decisions, interagency planning meetings and public scientific conferences, as well as coordination of joint studies to investigate pharmaceuticals and other related contaminants in the environment and biological outcomes related to exposure. This workgroup may also provide a means to facilitate interagency consultation on implications of research and analyses derived from shared information.

C. Sharing Confidential and Other Non-Public Information

The Parties will share information consistent with applicable statutes and regulations. The Parties 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 Freedom of Information Act (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., Trade Secrets Act (18 USC 1905)), the Privacy Act (5 USC 552a), other Freedom of Information Act exemptions not mentioned above (5 USC 552(b)), the Federal Food, Drug, and Cosmetic Act (21 USC 301 et seq.), and the Health Insurance Portability and Accountability Act (HIPAA), Pub. L. 104-191). Pursuant to Federal Food, Drug, and Cosmetic Act section 301(j) (21 USC 331(j)), FDA will not reveal to any Party any method or process which is entitled to protection as a trade secret.

Access to the confidential and other non-public information shared under this MOU shall be restricted to authorized federal 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 authorized 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.

The Parties agree to promptly notify the other agencies of any actual or suspected unauthorized disclosure of the confidential and other non-public information shared under this MOU.

If an agency in receipt of information under this MOU receives a FOIA request for confidential and other non-public information, it will refer the request to the agency where the information originated for the latter agency to respond directly to the requestor regarding the release-ability of the information at issue. In such cases, the agency making the referral will notify the requestor that a referral has been made and that a response will be issued directly from the other agency.

D. Procedures for Inter-Agency Sharing of Confidential and other Non-Public Information

To the extent confidential and other non-public information will be shared pursuant to this MOU, the Parties agree to follow the procedures outlined below. Procedures for sharing confidential and other non-public information amongst workgroup members will be handled separately.

a. The requesting Party will agree in writing, by using the model request letter (or a reasonable, mutually agreed upon letter variation), not to disclose any shared non-public information in any manner not authorized by law or regulation, including disclosure in publications and public meetings.

b. The sharing Party will include a transmittal letter along with any agency information shared. The transmittal letter will indicate the type of information (e.g., confidential commercial information, personal privacy, pre-decisional, etc.). A model transmittal letter is attached. The shared documents containing non-public information should be stamped "Do not disclose without permission of FDA/ [or] [Insert Name of Participating Party]" whichever is applicable.

c. The requesting Party 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 Party determines that employees other than those identified in the original request have a need to know the requested information, then an update to the request letter will be supplied to the sharing Party before the requesting Party distributes the information to those employees. The unit official who signs the request letter will be responsible for ensuring that there are no inappropriate recipients of the information.

d. The requesting Party will promptly notify the contact person or designee of the sharing Party of any attempt by a third Party to obtain shared non-public information by compulsory process, including, but not limited to, a FOIA request, subpoena, discovery request, or litigation complaint or motion.

e. If the requesting Party wishes to disclose shared information that the sharing Party has designated as non-public, the requesting Party will ask the sharing Party whether the information's non-public status has changed, and if so, will first obtain written confirmation and permission from the sharing Party before disclosing that information.

f. If the requesting Party receives a Freedom of Information Act (FOIA) request for shared information, the requesting Party will: (a) refer the FOIA request to the information-sharing contact person or designee for the sharing Party to respond directly to the FOIA requester regarding the release-ability of the information, and (b) notify the FOIA requester of the referral and that a response will issue directly from the sharing Party. The requesting Party will leave all final disclosure decisions up to the sharing Party, including decisions on whether the records are responsive and whether they must be disclosed.

g. The requesting Party will notify the sharing Party before complying with any judicial order that compels the release of shared non-public information, so that the Parties may determine the appropriate measures to take, including, where appropriate, legal action."

E. Dissemination of Workgroup Findings

The Parties agree that the public dissemination of workgroup findings should clearly indicate that the dissemination: 1) does not necessarily represent the position of the workgroup as a whole (unless there is a clear, verifiable consensus); and 2) that the dissemination does not necessarily represent or constitute the policy of any of the agencies Party to this agreement. The Parties will obtain prior approval of all press releases, published advertisements, or other statements intended for the public that refer to or are made in the name of the workgroup.

V. Duration of MOU

This MOU, when accepted by the named Parties, will become effective when approved by the indicated signatories for EPA/OW, USDA/ARS, HHS/FDA, and DOI/USGS and will continue in effect for a five year period from the date of the latest signature unless the Parties decide otherwise in writing, and may be modified by mutual written consent at any time. Any Party may withdraw from this MOU by providing written notice to the other Parties. The MOU will be modified to reflect this change and be effective upon the sixtieth (60) calendar day following notice, unless a later date is set forth. The protection of shared information shall survive the termination of this MOU or a Party's withdrawal from the workgroup. The Parties agree to evaluate the MOU at least once in the five-year period of the MOU at which time the Parties may agree to continue, modify, or cancel the MOU. This MOU may be modified or amended by written agreement of the Parties.

VI. Source of Funding

This MOU does not constitute a fiscal or funds obligating document. None of the activities outlined in this memorandum currently requires the exchange of funds, property or services between the Parties. Each Party to this MOU recognizes the other's responsibility to fund and carry out its own activities subject to, and to the extent made possible, by the availability of appropriated funds and no funds will be transferred under this MOU. Any specific collaborative activities arising from this MOU that require transfer of funds shall be the subject of a separate agreement. Any endeavor involving reimbursement or contribution of funds between the Parties to the MOU will be handled in accordance with applicable laws, regulations, and procedures. Such endeavors will be outlined in separate interagency agreements that shall be made in writing by representatives of both Parties and shall be independently authorized by appropriate statutory authority.

VII. Points of Contact

The following individuals will serve as the Steering Committee and designated points of contact for this MOU:

EPA/ORD:

Hal Zenick
Office of Research and Development
Director, National Health and Environmental Effects Research Laboratory
109 T.W. Alexander Drive
Mail Code B305-01
Research Triangle Park, NC 27709
919-541-2282

EPA/OW:

Elizabeth Southerland
Office of Water
Office Director, Office of Science and Technology
1200 Pennsylvania Ave. NW
Mail Code 4304T
Washington, DC 20460
202-566-0328

USDA/ARS:
Matt C. Smith
National Program Leader, Natural Resources and Sustainable Agricultural Systems
5601 Sunnyside Ave
Beltsville, Md, 20705-5148
301-504-4613

HHS/FDA:
Douglas C. Throckmorton
Deputy Center Director for Regulatory Programs, Center for Drug Evaluation and Research
10903 New Hampshire Ave.
Silver Spring, MD 20903
301-796-5400

DOI/USGS:
Herbert Buxton
Coordinator, Toxic Substances Hydrology Program
810 Bear Tavern Rd
Trenton, NJ 08628-1022
609-771-3944

Each Party may designate new Steering Committee representatives/points of contact at any time by notifying the other Parties in writing. If, at any time, an individual designated as a Steering Committee representative under this agreement becomes unavailable to fulfill those functions, the representative's Party will name a new representative within 2 weeks and notify the other Parties in writing.

Approvals:

Approved and Accepted
for the EPA/Office of Water
Signed by: _____
Nancy Stoner
Acting Assistant Administrator
Office of Water
Date: 12/18/12

Approved and Accepted
for the HHS/Food & Drug Administration
Signed by: _____
Dr. Douglas C. Throckmorton
Deputy Director, Center for Drug Evaluation and Research
Office of the Center Director
Date: _____

Approved and Accepted
for the USDA/Agricultural Research Service
Signed by: _____
Steven Shafer
Deputy Administrator
Natural Resources and Sustainable Agricultural Systems
Date: _____

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[redacted] Ione L. Taylor
[redacted] Associate Director
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Date: _____

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Natural Resources and Sustainable Agricultural Systems
Date: Nov. 26, 2012

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Dr. Douglas C. Throckmorton
Deputy Director, Center for Drug Evaluation and Research
Office of the Center Director
Date: 11/30/12

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Deputy Administrator
Natural Resources and Sustainable Agricultural Systems
Date: _____

Approved and Accepted
for the DOI/US Geological Survey
Signed by: [redacted]
[redacted] Ione L. Taylor
[redacted] Associate Director
US Geological Survey
Date: 11/29/2012

Model Language for Information Sharing Request from Participating Partner(s) to FDA

MOU Control No. (Insert number)

This letter accompanies agency records the (Participating Partner(s)) is sharing with the Food and Drug Administration (FDA) in response to FDA's request, dated _____. These agency records contain one or more of the following categories of nonpublic information, including information the public disclosure of which may be prohibited by law.

(Participating Partner(s)) checks applicable items below

____ Trade secrets

____ Confidential commercial or financial information

____ Information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy

____ Information subject to the Privacy Act

____ Intra-agency records

____ Records or information compiled for law enforcement purposes

____ Information protected for national security reasons; or

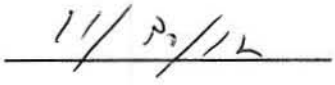
____ Other

FDA shall notify the appropriate office of the information-sharing agency if there are any attempts to obtain shared information by compulsory process, including but not limited to, Freedom of Information Act requests, subpoenas, discovery requests, and litigation complaints or motions.

FDA shall notify the information-sharing agency before complying with any judicial order that compels the release of such information that FDA and Partner(s) may take appropriate measures, including filing a motion with the court or an appeal.

[Party] has agreed, by this letter or e-mail and by a signed request letter dated _____, not to publically disclose the above-described information without prior written permission of FDA. [Party] acknowledges that applicable laws and regulations may prohibit the disclosure of such information. See, e.g., 21 U.S.C. section 331(j); 18 U.S.C. section 1905, 21 C.F.R. Parts 20 and 21, 45 CF.R. Parts 5 and 5b and 42 U.S.C. Section 241(d).

Name



Date