

OLSSON, FRANK AND WEEDA, P.C.

ATTORNEYS AT LAW

SUITE 400

1400 SIXTEENTH STREET, N.W.

WASHINGTON, D.C. 20036-2220

(202) 789-1212

FACSIMILE (202) 234-3550

PHILIP C. OLSSON
RICHARD L. FRANK
DAVID F. WEEDA (1948-2001)
DENNIS R. JOHNSON
ARTHUR Y. TSIEN
JOHN W. BODE*
STEPHEN D. TERMAN
MARSHALL L. MATZ
MICHAEL J. O'FLAHERTY
DAVID L. DURKIN
NEIL F. O'FLAHERTY
PAMELA J. FURMAN
BRETT T. SCHWEMER
TISH E. PAHL
ROBERT A. HAHN

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA
IS LIMITED TO MATTERS AND PROCEDURES
BEFORE FEDERAL COURTS AND AGENCIES

STEPHEN L. LACEY
EVAN P. PHELPS
VALERIE B. SOLOMON
JOLYDA O. SWAIM
KATHRYN E. BALMFORD

COUNSEL

NAOMI J.L. HALPERN

OF COUNSEL

JUR T. STROBOS
JACQUELINE H. EAGLE
KENNETH D. ACKERMAN
MARK L. ITZKOFF
DAVID A. BIEGING

SR. GOVERNMENT AFFAIRS ADVISOR

JOHN R. BLOCK
CHARLES W. STENHOLM
BRIAN E. JOHNSON
SALLY S. DONNER
BRENT W. GATTIS

MEMORANDUM

November 21, 2005

BY ELECTRONIC MAIL

FROM: Olsson, Frank and Weeda, P.C.

RE: FDA Final Guidance on Records Access

The Food and Drug Administration (FDA) has issued a final guidance document explaining how the agency intends to exercise its records access authority under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (full text available at: <http://www.cfsan.fda.gov/~dms/secgui13.html>). This final guidance contains only minor changes from FDA's draft guidance, which was published in December 2004.

The final guidance explains when FDA will invoke its records access authority, the procedures FDA will follow in doing so, and the scope of records access requests. FDA intends to exercise records access authority "whenever the statutory criteria are satisfied, whether or not intentional adulteration is known or suspected." Thus, FDA will seek records access when: (1) FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals; and (2) the records are needed in making such a determination. FDA will not invoke this new records access authority during inspections unless these criteria are met.

The scope of a record request will depend upon the particular circumstances. FDA may request access to records related to the manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of the suspect article of food. The agency also may request records of the immediate previous sources and immediate subsequent recipients of the suspect article of food. While FDA may not obtain access to certain records (*e.g.*, recipes for food, financial data, pricing data, personnel data, research data, or sales data other than shipment data regarding sales), FDA does have authority to access a food's list of ingredients.

FDA District Offices will not request records under this authority without the approval of headquarters. Before a request for records is made, FDA will follow internal procedures that involve the appropriate FDA Center (either the Center for Food Safety and Applied Nutrition or the Center for Veterinary Medicine), the Emergency Operations Center, the Office of Enforcement, and the Office of General Counsel. When a records request is made, an FDA investigator or other FDA personnel will present appropriate credentials and a written Form FDA 482c (Notice of Inspection – Request for Records) to the owner, operator, or agent in charge of the facility in question. The FDA investigator also will inform such person of the records requested and FDA's legal authority to access such records. FDA intends to request access to records at reasonable times, within reasonable limits, and in a reasonable manner.

We hope this information is helpful. If you have any questions, please contact Bob Hahn at (202) 518-6388 or rhahn@ofwlaw.com.

OFW:cr