

PHILIP C. OLSSON
RICHARD L. FRANK
DAVID F. WEEDA (1948-2001)
DENNIS R. JOHNSON
ARTHUR Y. TSIEN
STEPHEN D. TERMAN
MARSHALL L. MATZ
MICHAEL J. O'FLAHERTY
DAVID L. DURKIN
NEIL F. O'FLAHERTY
BRETT T. SCHWEMER
STEPHANIE HERSETH SANDLIN*
TISH E. PAHL
ROBERT A. HAHN
EVAN P. PHELPS
GARY H. BAISE
KATHRYN E. BALMFORD
FREDERICK H. BRANDING*

*PRACTICE WITHIN THE DISTRICT OF COLUMBIA
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LAW

OLSSON FRANK WEEDA TERMAN MATZ PC

THE WATERGATE
600 NEW HAMPSHIRE AVENUE NW
SUITE 500
WASHINGTON, DC 20037

(202) 789-1212 • FAX (202) 234-3550
WWW.OFWLAW.COM

Brett T. Schwemer - Principal
Direct (202) 518-6359 / Fax (202) 234-3550
bschwemer@ofwlaw.com

BRUCE A. SILVERGLADE
JOLYDA O. SWAIM
JONATHAN M. WEINRIEB
STEWART D. FRIED

COUNSEL

ROGER R. SZEMRAJ
ANSON M. KELLER
CASPER E. ULDRIKS

OF COUNSEL

KENNETH D. ACKERMAN
MARK L. ITZKOFF
ELLIOT BELILOS
JUR T. STROBOS, M.D.

SENIOR POLICY ADVISORS

JOHN R. BLOCK
CHARLES W. STENHOLM
GEORGE McGOVERN
SALLY S. DONNER
BRENT W. GATTIS

BARBARA J. MASTERS, D.V.M.
WILLIAM G. IMBERGAMO

MEMORANDUM

May 23, 2012

BY ELECTRONIC MAIL

FROM: Brett T. Schwemer
Olsson Frank Weeda Terman Matz PC

RE: FSIS Launches Electronic Label Submission Approval System

On May 21, 2012, the Food Safety and Inspection Service (FSIS) issued a news release on its website announcing that it has launched its electronic Label Submission Approval System (LSAS). The agency states that this new system will “expedite and simplify the review process for meat, poultry and egg product labels.” The news release is available at:

http://www.fsis.usda.gov/News_&_Events/NR_052112_01/index.asp.

The agency has also made available on its website several documents intended to assist establishments in using the LSAS, including:

- A User Guide for Industry, providing step-by-step instructions for performing industry tasks within LSAS,
http://www.fsis.usda.gov/PDF/LSAS_Industry_User_Guide_052112.pdf;

- Instructions on accessing the systems using Level 2 USDA-eAuthentication, http://www.fsis.usda.gov/PDF/LSAS_Enrollment_Screen_Guide.pdf.
<http://www.eauth.egov.usda.gov/>;
- A Frequently Asked Questions document, http://www.fsis.usda.gov/PDF/FAQs_LSAS.pdf; and
- Other information, including agency contact information for technical questions, FSIS presentations and other background information, regarding the LSAS. http://www.fsis.usda.gov/Regulations_&Policies/label_Submission_Approval_System/.

Overview of the LSAS

The LSAS is a “secure” web-based software application that integrates and implements an electronic label application process for establishments to submit label applications and appeals. FSIS states that the benefits of the system include:

- The ability to submit label applications, appeals, and supporting information electronically via the Internet;
- Alerts that will notify users of errors in label applications at the time of submittal;
- The ability for establishments to track the status of label applications or appeals electronically;
- Enhanced communication mechanisms, such as messaging within LSAS, which will allow LPDD to communicate problems with labels immediately and permit the submitter to correct the issues and resubmit the labels more expeditiously;
- The ability for establishments to obtain prior approvals as well as information from label application forms, such as ingredients, processes, special claims, and other specific label related information, from an electronic database; and
- An option, called the Generic Label Advisor (GLA), to assist an establishment in determining if a label can be generically approved.

Establishments wishing to use the LSAS will only need a working Internet connection, Level 2 e-Authentication, and Adobe Reader. If an establishment uses an in-house software system that incorporates the current FSIS paper application form (FSIS Form 7234-1), there is a mechanism to incorporate that information into the LSAS. Specifically, the LSAS provides a standard, computer format (XML) to interface with the LSAS system, allowing establishment data to be imported and processed into LSAS. Instructions for using this feature are in the LSAS User Guide.

As noted above, all users of LSAS are required to have a Level 2 e-Authentication user ID and password. Once authorized to use LSAS, the functionality and data to which users have access in LSAS will depend on the user's role and assignments identified in LSAS. Factors that define a user class include responsibilities, skill level, work activities, and mode of interaction with the system.

Continuation of Traditional Label Application Process

Importantly, the FSIS Labeling and Program Delivery Division (LPDD *will* continue to allow establishments to submit paper labels for approval if they do not wish to use the LSAS. These labels would be reviewed on a "first come-first serve" basis with any electronic file labels that are submitted. However, it is not expected that approval for paper labels will be as timely as labels submitted via e-file due to delays in the mail system as well as the need for LPDD to manually enter the paper labels in the electronic LSAS.

Child Nutrition Labels

Child Nutrition labels can also be processed in LSAS. If a CN label is submitted through LSAS, LSAS will direct the application to AMS technical staff, which has access to the system. Once AMS approves the label, LSAS will re-direct the label to the LPDD for further evaluation and approval. Submitters will be able to track this process through LSAS.

Emergency Labels

The LSAS will allow submitters to indicate whether a label requires prompt review under "extraordinary circumstances" (EC). If a submitter checks the "EC" box during a submission, LSAS will redirect the label application to an "EC Gatekeeper." The "EC Gatekeeper" will determine whether the label application qualifies under EC. If it does,



the label application is sorted to the top of the LPDD pool, behind any existing EC type applications there were already ahead of it in the queue.

Generic Label Approval

As noted above, the LSAS provides a GLA wizard that will assist submitters in determining which labels can be generically approved. If a label qualifies for generic approval, LSAS will allow the submitter print out a certificate that indicates this fact. The certificate could then be used to provide proof to Inspection Program Personnel that a particular label qualifies for generic label approval.

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We hope that this memorandum proves useful. If you have any questions or need further information, please contact us.

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