

Generically Approved Label Record Assessment Standard Operating Procedures: Pilot Project

Notification

2 Weeks prior to the first assessment

- A Food Safety and Inspection Service (FSIS) constituent update will be published announcing the onset of the pilot project.
- A meeting will be held with affected District Offices to discuss the selected establishments, required resources (if any) and dates of the assessments.

2 Weeks prior to each assessment, a letter will be sent to the selected establishment, the District Office, the Front Line Supervisor (FLS) and the Inspector-In-Charge (IIC) to

- a) Provide the date(s) for the assessment
- b) Request the establishment ensure that all labeling records are available for assessment
- c) Explain potential consequences of the assessment to the establishment (temporary label approval, label approval rescindment)
- d) Describe the documentation and reports that the establishment, the Office of Field Operations (OFO), and the Office of Program and Policy Development (OPPD) will receive.

Assessment

Two labeling subject matter experts (SMEs) and one policy analysis SME will attend each assessment. The SMEs will travel to the establishment on the first day of the assessment. The SMEs will review each label record to determine if it is a generically approved label record. The SMEs will assess each generically approved label record, documenting any identified deficiencies.

When a deficiency is identified, the SMEs will determine if the deficiency has public health significance. If it is determined to have public health significance, the SMEs will contact the IIC or FLS to alert them to the deficiency. When it is determined not to have public health significance, the SMEs will inform the establishment of the deficiency. If the establishment chooses to apply for temporary approval to continue use of the deficient label until compliant labels can be printed, the establishment will provide a copy of the deficient label record to the SMEs to be kept with a record of temporary approval in OPPD's Label Submission and Approval System.

Documentation

At the close of each assessment, the SMEs will provide the establishment, the District Manager, the FLS, and the IIC with a letter of their findings. The report will include:

- 1) The total number of label records assessed;
- 2) The number of label records determined to be generically approved;
- 3) A description of any deficiencies found in the assessed label records; and
- 4) Any requested temporary approvals for label records with non-public-health-significant deficiencies.

Reporting

At the conclusion of the pilot project, a report of the findings will be prepared for the assessed establishments, OFO, and OPPD. This report will be devoid of identifying information for the assessed establishments. In addition, a data chart that identifies the findings from each establishment and a short report listing recommended changes to the SOP for ongoing assessments will be provided to the aforementioned FSIS offices.

