

Questions and Answers on FSIS Directive 7000.4 “Verifying Certain Transferred Labeling”

Question: Does this cancel FSIS Directive 7221.1?

Answer: No, FSIS Directive 7221.1 describes the Agency’s procedures for the transfer of labels in general terms. The Agency issued FSIS Directive 7000.4 to provide additional instruction for inspection program personnel (IPP) to follow when one establishment (“the transferring establishment”) has transferred to another establishment (“the receiving establishment”) labeling with its own pre-printed establishment number. Labeling that does not bear a pre-printed establishment number can continue to be transferred following the procedures outlined in FSIS Directive 7221.1.

Question: Do we need to acquire approval from Washington to transfer labels with a pre-printed establishment number?

Answer: Not necessarily. Effective January 12, 2009, a receiving establishment using transferred labeling (e.g., immediate container labels and other packaging materials) bearing a pre-printed establishment number (e.g., the transferring establishment’s number) and code mark are to submit for temporary approval in order to use the labeling. An establishment does not need to submit for temporary approval *if* it corrects the pre-printed establishment number (e.g., the receiving establishment places its own establishment number over the establishment number of the shipping establishment by using a pressure sensitive sticker) before it uses the labeling. Labeling that does not bear a pre-printed establishment number can continue to be transferred following the procedures outlined in FSIS Directive 7221.1.

Question: Our Company started using transferred labeling in December 2008 bearing a pre-printed establishment number. Our establishment currently code-marks the product in a manner that is acceptable to the IIC while we have new labeling approved and printed. On January 12th when FSIS Directive 7000.4 becomes effective, will we not be in compliance because we didn’t obtain temporary approval to use the labeling with a code-mark that was shipped in December?

Answer: If an establishment is using transferred labeling with a pre-printed establishment number and code mark *prior* to January, 12, 2009, it can continue to do so on a temporary basis without submitting for temporary approval while pressure sensitive stickers are made or new labeling is printed. However, any labeling transferred prior to January 12, 2009, should not be used for more than 60 days after the implementation of the Directive (i.e., March 12, 2009). *All new uses* of transferred labeling implemented after January 12, 2009, bearing a pre-printed establishment number and code mark will require submitting the labeling to LPDD for temporary approval.

Question: How long will it take for the Labeling and Program Delivery Division (LPDD) to respond to our request for temporary approval?

Answer: LPDD evaluates all requests for temporary approval in the order in which they are received. If an establishment believes it has “extraordinary circumstances” for which it needs immediate evaluation of the request for temporary approval, an accelerated label evaluation can be requested. The procedures for requesting an evaluation of labeling under extraordinary circumstances are described in the following FSIS guidance document (http://www.fsis.usda.gov/Regulations_&Policies/LabelEvaluationProcedures/index.asp). However, it should be understood that the use of transferred labeling bearing the transferring establishment’s number is only to be used in limited circumstances. It is establishments’ responsibility to plan for foreseeable circumstances.

Question: Can we request an extension from LPDD if we cannot design, submit for approval and print the labels within 60 days?

Answer: Yes, if an establishment has circumstances for which it believes an extension of temporary approval is needed, it may submit for an extension. LPDD will evaluate the circumstances of each request on a case by case basis.

Question: Does the Directive apply to the transfer of shipping containers that bear a pre-printed establishment number?

Answer: Yes, the Directive applies to the transfer of all labeling (e.g., immediate container labeling and shipping container labeling) that bears a pre-printed establishment number.

Question: Can the code mark described in FSIS Directive 7000.4 just be the receiving establishment's establishment number?

Answer: No, FSIS believes that the application of *only* the receiving establishment's number could create confusion for the establishment, the public, or the Agency in the event of a voluntary market withdrawal or product recall. The code mark can, however, incorporate the receiving establishment's number. For example, FSIS Directive 7000.4 provides an example of an acceptable code mark as a numeric code consisting of the lot number *and* the receiving establishment's number.

Question: Our Company owns several different establishments. Can our Company transfer labeling (with a pre-printed establishment number) from one establishment to another sister establishment for use with a code mark without receiving temporary approval?

Answer: No, the receiving establishment will need to submit for temporary approval to use labeling bearing the shipping establishment's pre-printed establishment number and code mark.