

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE	7000.4	12/8/08
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NOTE: DO NOT IMPLEMENT THIS DIRECTIVE UNTIL JANUARY 12, 2009

VERIFYING CERTAIN TRANSFERRED LABELING

I. PURPOSE

This directive supplements the instructions for performing the 04B04 general labeling verification procedure in FSIS Directive 7000.1. It adds procedures for inspection program personnel (IPP) to follow when one establishment (“the transferring establishment”) has transferred to another establishment (“the receiving establishment”) labeling with official marks and its own pre-printed establishment number.

Key Points Covered

- IPP are to verify that labels with establishment numbers transferred between establishments are used in accordance with the regulations.

- IPP are to verify that labels code-marked for tracking purposes are used in accordance with the temporary approval terms

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

FMIA, especially 21 U.S.C. 601(n), 610, 611

PPIA, especially 21 U.S.C. 453(h), 458(a), 458(b)

9 CFR 301.2, 317.1, 317.13, 317.4(f)(1), 320.1(b)(11), 320.4

9 CFR 381.1, 381 Subpart N, 381.132(f)(1), 381.138(b), 381.175(b)(6), 381.178

V. BACKGROUND

A. FSIS regulations (9 CFR 317.13 and 381.138(b)) allow an official establishment to transfer labels, wrappers, or containers bearing official marks with its establishment number to any other official establishment for temporary use. This transfer can only occur, however, in limited, special circumstances. For example, after a fire, an establishment may need to move its production to another facility. Likewise, to fill an unexpected large order, an establishment may need to arrange for temporary production at another facility. In these special circumstances, an establishment may transfer labels that bear its mark of inspection and establishment number to another establishment for use.

B. Labeling bearing an establishment's pre-printed mark of inspection and establishment number cannot be transferred, however, for normal or long-term use. An establishment that co-packs product for another establishment over an extended period, or a business entity that shifts production among several establishments that it owns, needs to apply approved labeling displaying the establishment number of the processing (receiving) plant to comply with 9 CFR 317.2(c)(5) and 381.123.

C. In a short-term situation, the establishment that receives transferred labeling needs to request temporary approval to use it (9 CFR 317.4(f)(1) and 381.132(f)(1)) with the establishment number of the transferring establishment because one or more labeling features (i.e., the establishment number and possibly the name and place of business of the manufacturer, packer, or distributor as described in 9 CFR 317.2(g) and 381.122)) may not comply with the regulations. The Labeling and Program Development Division (LPDD), which grants temporary approvals, looks for information supporting the request that explains why a transfer of labeling is needed, the transferring establishment's label approval, the date of labeling shipment, the quantity of labeling, the type of labeling material, and the prominent code that will be applied to labeling in order to track the product. FSIS has required for many years that receiving establishments using transferred labeling bearing a pre-printed establishment number (i.e., the transferring establishment's number) be code marked in order to identify the producing (receiving) establishment. The code mark is a unique identifier such as, a numeric code consisting of the lot number and the establishment number in which the product was produced. When LPDD grants temporary approval to use transferred labeling bearing a pre-printed mark of inspection and code mark, LPDD will provide a copy of the temporary approval to the IIC of the establishment using the transferred labeling (i.e. the receiving establishment).

D. The Agency has insisted on the use of this prominent code mark to help the receiving establishment, the public, and the Agency to identify and track the product. Easy identification of the product can be important if there is a problem leading, for example, to a voluntary market withdrawal or to a product recall. Alternatively, the receiving establishment can either correct the transferred labeling or use approved labeling bearing its own establishment number. The temporary approval will provide that transferred labeling bearing a pre-printed establishment number and prominent code mark can only be used for 60 days from the date of temporary approval unless the establishment number is corrected on the transferred labeling (e.g., covering the pre-

printed establishment number with a pressure sensitive sticker) to reflect the number of establishment in which the product is processed (that is, the receiving establishment's number).

E. If inspection personnel have any questions or concerns about an establishment's use of transferred labeling, they are to request to examine the temporary approval granted by LPDD in the establishments labeling records. Establishments are required to keep labeling records as described in 9 CFR Parts 320 and 381, Subpart Q.

VI. VERIFYING COMPLIANCE WITH FSIS' REGULATIONS ON THE USE OF TRANSFERRED LABELING BEARING A PRE-PRINTED ESTABLISHMENT NUMBER WHILE PERFORMING AN 04B04 PROCEDURE

A. If, while conducting an 04B04 labeling verification procedure, IPP encounter labels bearing another establishment's number, they are to verify that LPDD granted temporary approval for the establishment to use the transferred labeling. As stated above, LPDD's temporary approval is required to be available in the establishment's labeling records, and LPDD will provide a copy to the IIC. IPP are to verify that the establishment is using the appropriate code mark identified in the temporary approval. They are also to verify that the establishment does not use the code-marked labeling more than 60 days after the date of temporary approval.

B. IPP are to verify that transferred labeling used for more than 60 days complies with the regulations (9 CFR 317.2 (c)(5) or 381.123), i.e., it bears the number of the establishment in which the product was processed. An establishment can correct the labeling by placing a pressure-sensitive sticker bearing its own establishment number over the pre-printed establishment number. This type of labeling change is generically approved under 9 CFR 317.5 and 381.133. See link below:

[http://www.fsis.usda.gov/Regulations & Policies/Pressure Sensitive Stickers/index.asp](http://www.fsis.usda.gov/Regulations%20&%20Policies/Pressure%20Sensitive%20Stickers/index.asp).

C. IPP are to retain product as necessary, notify the OPPER Regional Office if product is shipped into commerce, and issue a Noncompliance Record (NR) under the 04B04 procedure code and cite 9 CFR 317.13 or 381.138(b) when:

1. the receiving establishment does not have temporary approval granted by LPDD in its labeling records to use transferred labeling bearing an establishment number other than its own with a code-mark;
2. the receiving establishment has received temporary approval to use transferred labeling bearing an establishment number other than its own but is not following the conditions of the temporary approval, e.g., it is not applying the appropriate code-mark specified in the temporary approval granted by LPDD;
3. the receiving establishment is using transferred labeling bearing appropriate code marks, but it is using the code marked labeling for more than 60 days

after the date of temporary approval; or

4. transferred labeling does not bear the correct inspection legend and establishment number (i.e., the number of the establishment in which the product was processed).

Refer all technical questions to the Policy Development Division (PDD) and all labeling questions to LPDD. Both divisions can be contacted by calling 1-800 233-3935 and following the menu options: for PDD press numbers 1 and then 5; for LPDD press numbers 1, 3, and then 1. You may also submit questions through *askFSIS* at <http://askfsis.custhelp.com>.



Assistant Administrator
Office of Policy and Program Development