
List of Subjects in 21 CFR Part 184
Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and re-delegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:


2. Section 184.1444 is amended by revising the second sentence in paragraph (a) by adding paragraph (b)(3) to read as follows:

§ 184.1444 Maltodextrin.
(a) * * * It is prepared as a white powder or concentrated solution by partial hydrolysis of corn starch, potato starch, or rice starch with safe and suitable acids and enzymes.
(b) * * * (3) Maltodextrin derived from rice starch meets the specifications of the Food Chemicals Codex, 4th ed. (1996), pp. 239 and 240, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 80 North Capitol St. NW., suite 700, Washington, DC.

L. Robert Lake, Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 314 and 600

[Docket No. 93N-0181]
RIN 0910-AA97

Expedited Safety Reporting Requirements for Human Drug and Biological Products; Correction

AGENCY: Food and Drug Administration, HHHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the Federal Register of October 7, 1997 (62 FR 52237), to include some conforming amendments that were inadvertently omitted. The final rule amended the expedited safety reporting regulations for human drug and biological products. This action is being taken to ensure the accuracy and consistency of the regulations.


FOR FURTHER INFORMATION CONTACT: Lajuania D. Caldwell, Office of Policy (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 7, 1997 (62 FR 52237), FDA amended, among other things, its regulations in § 314.80 Postmarketing reporting of adverse drug experiences (21 CFR 314.80) and § 600.80 Postmarketing reporting of adverse experiences (21 CFR 600.80). In that document, the agency inadvertently omitted conforming amendments to §§ 314.80(k) and 600.80(l) to correct the current cross-references to §§ 314.80(c)(1)(ii) and 600.80(c)(1)(ii). These paragraphs should reference §§ 314.80(c)(1)(iii) and 600.80(c)(1)(iii), respectively. This correction does not, in any way, alter the scope or intent of the October 7, 1997, document.

In final rule FR Doc. 97-26255, published on October 7, 1997 (62 FR 52237), make the following corrections:

§ 314.80 [Corrected]
1. On page 52251, in mandatory instruction 8, in the second column, beginning in line 7, the phrase, “;” and by removing paragraph (j) and redesignating paragraphs (k) and (l) as paragraphs (j) and (k), respectively, “;” is corrected to read, “;”; by removing paragraph (j), redesignating paragraphs (k) and (l) as paragraphs (j) and (k), respectively; and by revising the last sentence in newly redesignated paragraph (k).”

2. On page 52252, in the second column, in § 314.80, the last sentence of redesignated paragraph (k) is correctly revised to read as follows:

§ 600.80 [Corrected]
3. On the page 52252, in the second column, in mandatory instruction 10, beginning in line 5, the phrase, “;” and by removing paragraph (j) and redesignating paragraphs (k), (l), and (m) as paragraphs (j), (k), and (l),
respectively,” is corrected to read, “; by removing paragraph (j), redesignating paragraphs (k), (l), and (m) as paragraphs (j), (k), and (l), respectively; and by revising the last sentence in newly redesignated paragraph (l).”

4. On page 52253, in the second column, in § 600.80, the last sentence of newly redesignated paragraph (l) is correctly revised to read as follows:

§ 600.80 Postmarketing reporting of adverse experiences.

* * * * *

(l) * * * For the purposes of this provision, this paragraph also includes any person reporting under paragraph (c)(1)(i) of this section.


William K. Hubbard,
Associate Commissioner for Policy Coordination.

[FR Doc. 98–7833 Filed 3–25–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor address for Koffolk, Inc.

EFFECTIVE DATE: March 26, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Koffolk, Inc., One Parker Plaza, Fort Lee, NJ 07024, has informed FDA of a change of sponsor address to P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor address.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:


2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the sponsor address for “Koffolk, Inc.” and in the table in paragraph (c)(2) in the entry for “063271” by revising the sponsor address to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(c) * * *

(1) * * *

Firm name and address

Drug labeler code

Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067. 063271

(2) * * *

Drug labeler code

Firm name and address

063271

Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067.