6. Food Chemicals Codex, 4th ed., National Academy Press, Washington, DC, pp. 239 and 240, 1996.

7. Evans, R. B., and O. B. Wurzburg, ''Production and Use of Starch Dextrins,'' *Starch: Chemistry and Technology*, vol. 2, edited by R. L. Whistler, and E. F. Paschall, Academic Press, Inc., New York, pp. 253–278, 1967.

8. ''Food Additives and Contaminants Committee Report on Modified Starches,'' United Kingdom Ministry of Agriculture, Fisheries and Food, FAC/REP/31, Her Majesty's Stationery Office, London, p. 5, 1980.

9. ''Definition of Maltodextrin,'' European Starch Associations, Circular Letter Stex 4/88, February 1988.

10. Memorandum from the Chemistry Review Branch to the Direct Additives Branch, ''Maltodextrin from Rice,'' dated January 13, 1997.

11. ''Paselli SA2,'' *Technical Bulletin*, No. 5.12.33.188EU, AVEBE America, Inc., Princeton, NJ.

12. ''INSTANT N–OIL II,'' *Techical Service Bulletin*, No. 15889–238, National Starch and Chemical Corp., Bridgewater, NJ.

13. Warthesen, J. J., ''Analysis of Saccharides in Low-Dextrose Equivalent Starch Hydrolysates Using High-Performance Liquid Chromatography,'' *Cereal Chemistry*. vol. 61, No. 2, pp. 194 and 195, 1984.

14. Zuber, M. S., ''Genic Control of Starch Development'' *Starch: Chemistry and Technology*, edited by R. L. Whistler and E. F. Paschall, Academic Press, Inc., New York, pp. 45, 61–63, 1965.

15. Whistler, R. L., and J. R. Daniel, ''Starch,'' *Kirk-Othmer's Encyclopedia of Chemical Technology*, 3d ed., vol. 21, edited by J. Brown, C. I. Eastman, Galojuch, et al., John Wiley & Sons, New York, pp. 492–507, 1983.

16. ''Maltodextrin; Proposed Affirmation of GRAS Status as Direct Human Food Ingredient,'' 47 FR 36443, August 20, 1982.

17. ''Specifications for the Identity and Purity of Food Additives and Their Toxicological Evaluation,'' *FAO Nutrition Meetings Report Series*, No. 46 and *WHO Technical Report Series*, No. 445, pp. 13 and 14, 1970.

18. ''Toxicological Evaluation of Some Food Colours, Emulsifiers, Stabilizers, Anti-Caking Agents, and Certain Other Substances,'' *FAO Nutrition Meetings Report Series*, No. 46A, p. 62 and WHO/FOOD ADD./70.36, 1970.

19. Memorandum from the Additives Evaluation Branch, to the Direct Additives Branch, ''GRP 2G0380–GRAS Affirmation Petition for Maltodextrin Derived from Derived Rice: Division of Health Effects Evaluation Review (DHEE; HFS–225),'' dated August 3, 1993.

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 redelegated 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:

Authority: 21 U.S.C. 321, 342, 348, 371.

2. Section 184.1444 is amended by revising the second sentence in paragraph (a) and 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, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

Dated: March 3, 1998.

L. Robert Lake,

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

[FR Doc. 98–7894 Filed 3–25–98; 8:45 am]

BILLING CODE 4160–01–F

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, HHS.

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.

EFFECTIVE DATE: April 6, 1998.

FOR FURTHER INFORMATION CONTACT: LaJuana 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 amendatory 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:

§ 314.80 Postmarketing reporting of adverse drug experiences.

* * * * *

(k) * * * For purposes of this provision, the term ''applicant'' also includes any person reporting under paragraph (c)(1)(iii) of this section.

§ 600.80 [Corrected]

3. On the page 52252, in the second column, in amendatory 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)(iii) of this section.

Dated: March 18, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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

BILLING CODE 4160–01–F

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:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

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.
* * *	* * * *