2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33 and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

** * *Effective April 30, 1992*

Camden, AR—Harrell Field, VOR/DME RWY 36, Amdt. 7
Hot Springs, AR—Memorial Field, VOR–1 RWY 5, Amdt. 15
Hot Springs, AR—Memorial Field, VOR–2 RWY 5, Amdt. 3
Hot Springs, AR—Memorial Field, NDB RWY 5, Amdt. 6
Ukiah, CA—Ukiah Muni, LOC RWY 15, Amdt. 5
Melbourne, FL—Melbourne Regional, VOR RWY 9R, Amdt. 19
Melbourne, FL—Melbourne Regional, ILS RWY 9R, Amdt. 9
Junction City, KS—Freeman Field, NDB–B, Amdt. 2
Madisonville, KY—Madisonville Muni, VOR RWY 23, Amdt. 12
Madisonville, KY—Madisonville Muni, VOR/DME RNAV RWY 23, Amdt. 3
Paducah, KY—Ferrington Airpark, VOR/DME–B, Amdt. 3, Cancelled
Cape Girardeau, MO—Cape Girardeau Muni, VOR RWY 2, Amdt. 9
Cape Girardeau, MO—Cape Girardeau Muni, LOC/DME BC RWY 28, Amdt. 5
Cape Girardeau, MO—Cape Girardeau Muni, NDB RWY 10, Amdt. 8
Cape Girardeau, MO—Cape Girardeau Muni, ILS RWY 10, Amdt. 9
Fredericktown, MO—Fredericktown Muni, VOR–B, Amdt. 1
Fredericktown, MO—Fredericktown Muni, VOR/DME RWY 1, Amdt. 1
Broken Bow, NE—Broken Bow Muni, VOR RWY 14, Amdt. 3
Broken Bow, NE—Broken Bow Muni, NDB RWY 14, Amdt. 7
Norfolk, NE—Karl Stefan Memorial, VOR RWY 1, Amdt. 6
Norfolk, NE—Karl Stefan Memorial, VOR RWY 13, Amdt. 6
Norfolk, NE—Karl Stefan Memorial, VOR RWY 19, Amdt. 6
Norfolk, NE—Karl Stefan Memorial, VOR RWY 31, Amdt. 6
Mesquite, NV—Mesquite, VOR/DME–A, Orig.
Cross Keys, NJ—Cross Keys, VOR RWY 9, Amdt. 5
Belen, NM—Alexander Muni, VOR/DME–A, Amdt. 1
Binghamton, NY—Edwin A. Link Field/Broome Co., ILS RWY 16, Amdt. 6
Wurtsboro, NY—Wurtsboro-Sullivan County, VOR–A, Amdt. 2, Cancelled
Wurtsboro, NY—Wurtsboro-Sullivan County, VOR/DME RWY 5, Orig.
Ashtabula, OH—Ashtabula County, VOR RWY 8, Orig., Cancelled
Ashtabula, OH—Ashtabula County, VOR RWY 8, Orig.
Ashtabula, OH—Ashtabula County, VOR/DME RWY 26, Amdt. 6
Ashtabula, OH—Ashtabula County, VOR/DME RNAV RWY 26, Amdt. 6
Columbus, OH—Port Columbus Intl, LOC BC RWY 28R, Amdt. 6
Columbus, OH—Port Columbus Intl, NDB RWY 10L, Amdt. 7
Columbus, OH—Port Columbus Intl, NDB RWY 10R, Amdt. 7
Columbus, OH—Port Columbus Intl, NDB RWY 28L, Amdt. 13
Columbus, OH—Port Columbus Intl, ILS RWY 10L, Amdt. 15
Columbus, OH—Port Columbus Intl, ILS RWY 10R, Amdt. 6
Columbus, OH—Port Columbus Intl, ILS RWY 28L, Amdt. 26
Columbus, OH—Port Columbus Intl, RADAR–1, Amdt. 17
Hebron, OH—Buckeye Executive, VOR–A, Amdt. 5
Annville, PA—Millard, VOR/DME–A, Amdt. 3
Arlington, TN—Arlington Muni, LOC RWY 15, Amdt. 1
Arlington, TN—Arlington Muni, NDB RWY 15, Amdt. 7
Dyersburg, TN—Dyersburg Muni, VOR–A, Amdt. 16
Dyersburg, TN—Dyersburg Muni, VOR/DME RWY 4, Amdt. 2
Savannah, TN—Savannah-Hardin County, VOR/DME RWY 18, Amdt. 5
Savannah, TN—Savannah-Hardin County, NDB RWY 18, Amdt. 3
Dallas, TX—Redbird, VOR RWY 17, Amdt. 5
Dallas, TX—Redbird, VOR RWY 31, Amdt. 10
Dallas, TX—Redbird, NDB RWY 35, Amdt. 7
Dallas, TX—Redbird, ILS RWY 31, Amdt. 5
New Braunfels, TX—New Braunfels Muni, VOR/DME–A, Amdt. 8
New Braunfels, TX—New Braunfels Muni, NDB RWY 22, Amdt. 1
New Braunfels, TX—New Braunfels Muni, VOR/DME RNAV RWY 13, Amdt. 2
New Braunfels, TX—New Braunfels Muni, VOR/DME RNAV RWY 31, Amdt. 2
Abingdon, VA—Virginia Highlands, LOC RWY 24, Amdt. 1

** * * Effective April 2, 1992*

Covington/Cincinnati, OH, KY—Cincinnati/Northern Kentucky International, ILS RWY 18L, Amdt. 1
Covington/Cincinnati, OH, KY—Cincinnati/Northern Kentucky International, ILS RWY 36R, Amdt. 2
Frankfort, KY—Capital City, RADAR–1, Orig.
Allegan, MI—Padgham Field, VOR RWY 28, Amdt. 13
Kalamazoo, MI—Kalamazoo/Battle Creek Intl, VOR RWY 17, Amdt. 17
Kalamazoo, MI—Kalamazoo/Battle Creek Intl, VOR RWY 23, Amdt. 17
Kalamazoo, MI—Kalamazoo/Battle Creek Intl, VOR RWY 35, Amdt. 16
Kalamazoo, MI—Kalamazoo/Battle Creek Intl, LOC BC RWY 17, Amdt. 18
Kalamazoo, MI—Kalamazoo/Battle Creek Intl, NDB RWY 35, Amdt. 18
Kalamazoo, MI—Kalamazoo/Battle Creek Intl, ILS RWY 35, Amdt. 20
Kalamazoo, MI—Kalamazoo/Battle Creek Intl, RADAR–1, Amdt. 8
Columbus-West Point Starkville, MS—Golden Triangle Regional, ILS RWY 18, Amdt. 6
Morganton, NC—Morganton-Lenoir, RNAV RWY 3, Amdt. 3, Cancelled
Albany, OR—Albany Muni, VOR/DME–A, Amdt. 1
Jacksboro, TN—Campbell County, NDB RWY 23, Amdt. 4
Nashville, TN—Nashville International, ILS RWY 20L, Amdt. 2

** * * Effective February 12, 1992*

East Stroudsburg, PA—Birchwood-Pocono Airpark, VOR/DME RWY 32, Amdt. 3

[FR Doc. 92–4228 Filed 2–24–92; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 225, 500, 510, 511, 514, 558, 570, and 571

[Docket No. 91N–506]

Center for Veterinary Medicine Address Change; Editorial Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending certain of its regulations to reflect the change of address for the Center for Veterinary Medicine (CVM). FDA is also editorially changing the name "Office of Compliance" in 21 CFR 570.6 to "Office of Surveillance and Compliance." This action will ensure public notice of the current address of CVM and improve the accuracy and clarity of the regulations.

EFFECTIVE DATE: February 25, 1992.

FOR FURTHER INFORMATION CONTACT: Robert S. Brigham, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8737.

SUPPLEMENTARY INFORMATION: FDA is revising certain of its regulations to correct the address for CVM due to its recent relocation to 7500 Standish Pl., Rockville, MD 20855. The affected regulations are: 21 CFR 5.100, 225.115(b)(2), 500.27(d), 500.51(c), 510.112(e), 510.302(d), 510.310(f), 511.1(e), 514.1(d)(2), 558.5(c)(2), 558.15 (d) and (e), 570.6(e), and 571.1(c). FDA is also editorially changing in § 570.6 the name "Office of Compliance" to "Office of Surveillance and Compliance." These amendments are nonsubstantive, and notice and public procedure and

delayed effective date are unnecessary (5 U.S.C. 553 (b)(3)(B) and (d)).

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 225

Animal drugs, Animal feeds, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Polychlorinated biphenyls (PCB's).

21 CFR Part 510

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

21 CFR Part 511

Animal drugs, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

21 CFR Part 570

Animal feeds, Animal foods, Food additives.

21 CFR Part 571

Administrative practice and procedure, Animal feeds, Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 5, 225, 500, 510, 511, 514, 558, 570, and 571 are amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50; 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101–2672 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1–300ff); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

§ 5.100 [Amended]

2. Section 5.100 *Headquarters* is amended in footnote number one by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

PART 225—CURRENT GOOD MANUFACTURING PRACTICE FOR MEDICATED FEEDS

3. The authority citation for 21 CFR part 225 continues to read as follows:

Authority: Secs. 501, 502, 512, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360b, 371, 374).

§ 225.115 [Amended]

4. Section 225.115 *Complaint files* is amended in paragraph (b)(2) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

PART 500—GENERAL

5. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: Secs. 201, 301, 402, 403, 409, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371).

§ 500.27 [Amended]

6. Section 500.27 *Methylene blue-containing drugs for use in animals* is amended in paragraph (d) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

§ 500.51 [Amended]

7. Section 500.51 *Labeling of animal drugs; misbranding* is amended in paragraph (c) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

PART 510—NEW ANIMAL DRUGS

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

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.112 [Amended]

9. Section 510.112 *Antibiotics used in veterinary medicine and for nonmedical purposes; required data* is amended in paragraph (e) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

§ 510.302 [Amended]

10. Section 510.302 *Reporting forms* is amended in paragraph (d) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

§ 510.310 [Amended]

11. Section 510.310 *Records and reports for new animal drugs approved before June 20, 1963* is amended in paragraph (f) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

12. The authority citation for 21 CFR part 511 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 360b, 371).

§ 511.1 [Amended]

13. Section 511.1 *New animal drugs for investigational use exempt from section 512(a) of the act* is amended in paragraph (e) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

PART 514—NEW ANIMAL DRUG APPLICATIONS

14. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: Secs. 501, 502, 512, 701, 706, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360b, 371, 376, 381).

§ 514.1 [Amended]

15. Section 514.1 *Applications* is amended in paragraph (d)(2) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

16. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.5 [Amended]

17. Section 558.5 *New animal drug requirements for liquid Type B feeds* is amended in paragraph (c)(2) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

§ 558.15 [Amended]

18. Section 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the*

feed of animals is amended in paragraphs (d) and (e) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

PART 570—FOOD ADDITIVES

19. The authority citation for 21 CFR part 570 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

§ 570.6 [Amended]

20. Section 570.6 *Opinion letters on food additive status* is amended in paragraph (e) by removing "Office of Compliance" and replacing it with "Office of Surveillance and Compliance", and by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

PART 571—FOOD ADDITIVE PETITIONS

21. The authority citation for 21 CFR part 571 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371); sec. 301 of the Public Health Service Act (42 U.S.C. 241).

§ 571.1 [Amended]

22. Section 571.1 *Petitions* is amended in paragraph (c) by removing "5600 Fishers Lane, Rockville, MD 20857" and replacing it with "7500 Standish Pl., Rockville, MD 20855".

Dated: February 19, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-4274 Filed 2-24-92; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 184

[Docket No. 89G-0126]

Direct Food Substances Affirmed as Generally Recognized as Safe; Chymosin Enzyme Preparation Derived From Genetically Modified Kluyveromyces Marxianus (Hansen) Van Der Walt Variety Lactis (Dombrowski) Johannsen et Van Der Walt

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that the use of chymosin preparation derived by fermentation from genetically modified *Kluyveromyces marxianus* (Hansen) Van Der Walt variety *lactis* (Dombrowski) Johannsen et Van Der Walt (*K. marxianus* var. *lactis*) is generally recognized as safe (GRAS). This action is in response to a petition filed by Gist-brocades, Inc.

EFFECTIVE DATE: February 25, 1992.

FOR FURTHER INFORMATION CONTACT: Vincent Zenger, Center for Food Safety and Applied Nutrition (HFF-333), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), Gist-brocades, Inc., P.O. Box 241068, Charlotte, NC 28224, submitted a petition (GRASP 9G0349) requesting that its chymosin preparation (referred to as "chymosin" in the notice of filing of the Gist-brocades petition that FDA published in the **Federal Register** of May 10, 1989 (54 FR 20203)), which is derived from the fermentation of genetically modified *K. marxianus* var. *lactis*, be affirmed as GRAS for use as a direct human food ingredient. Chymosin is the principal enzyme in rennet, a GRAS food ingredient used for its milk-clotting activity, and is primarily responsible for that activity. Chymosin preparation is intended for use as a substitute for rennet.

To avoid confusion between chymosin, the enzyme, and chymosin, the enzyme preparation (in which chymosin is the principal active component, but which also may contain impurities), this document will use the term "chymosin" to refer to the enzyme and "chymosin preparation" to refer to the fermentation-derived chymosin enzyme preparation.

In the May 10, 1989, notice of filing, FDA gave interested parties an opportunity to submit comments to the Dockets Management branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. In response to the notice, FDA received one comment which was from a cheese manufacturer, and expressed a desire to have available an alternate source of chymosin. The comment contained no information relevant to the safety, functionality, environmental impact, or the GRAS status of the food use of the subject chymosin preparation. Thus, the comment requires no response by FDA.

II. Standards for GRAS Affirmation

Pursuant to § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence required for approval of the substance as a food additive and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). In its petition, Gist-brocades, Inc., relies upon scientific procedures to establish that its chymosin preparation is GRAS.

Rennet is an animal-derived enzyme preparation that is GRAS as specified in § 184.1685 (21 CFR 184.1685). Therefore, if published information shows that the principal active component of chymosin preparation is the same as that of rennet, and that the other components (i.e., the impurities) of the chymosin preparation, which may differ from the other components (i.e., the impurities) of rennet, do not render the use of the substance unsafe, then chymosin derived from *K. marxianus* var. *lactis* would present no more safety concern than rennet. If this is the case, FDA can affirm the chymosin preparation derived from *K. marxianus* var. *lactis* as GRAS for use as a replacement for rennet.

III. Safety

A. Introduction

Chymosin, also known as rennin, is the principal milk-clotting enzyme present in rennet (Ref. 1). Rennet is an enzyme preparation that will clot milk, forming curds and whey (Refs. 1 and 2). It is used to make cheese and other dairy products. Rennet has a long and extensive history of safe use in food and has been affirmed by FDA as GRAS in § 184.1685 (Refs. 3 and 4).

Food-grade rennet is an enzyme preparation that is isolated from the fourth stomach of calves, kids, or lambs. Commercially, it is generally derived by the aqueous extraction of unweaned calf stomachs. The aqueous extraction step is followed by purification steps and an acidification step to cleave prochymosin (the inactive precursor of chymosin) in the rennet into chymosin (Ref. 1).

There are two predominant forms of calf chymosin, chymosin A and chymosin B (Ref. 1). Foltmann et al. (Ref. 5) have shown that chymosin A and chymosin B differ by a single amino acid. In this document, the term

"chymosin" refers to either, or both, chymosin A and chymosin B.

Techniques developed in the early 1970's (frequently termed "recombinant DNA technology," or "cloning techniques") enable scientists to locate and to obtain a segment of deoxyribonucleic acid (DNA) containing a gene of interest. They are able to move that DNA segment into a vector (a DNA molecule that is easy to manipulate) and then introduce it into a new host organism where it can be correctly expressed (that is, produce the protein that it would have produced in the original organism). These techniques are well known to molecular biologists (Refs. 6 and 7).

B. Chymosin Component

Using cloning techniques, scientists in several laboratories have identified in the calf the prochymosin gene from which the chymosin in rennet is produced (Refs. 8, 9, and 10). Scientists have transferred the calf prochymosin gene into *K. marxianus* var. *lactis* as well as into other microorganisms (Refs. 8 through 16).

These scientists have used a variety of techniques to demonstrate that they have cloned full-length copies of the correct gene. Such techniques include: (1) DNA sequencing, whereby the putative cloned prochymosin gene was shown to have the nucleotide sequence that encodes the amino acid sequence of prochymosin (Refs. 8, 9, and 10); (2) nucleic acid hybridization, whereby the cloned DNA fragments or the ribonucleic acid molecules transcribed (copied) from the DNA fragments were shown to hybridize (i.e., specifically bind) with complementary DNA in the prochymosin gene (Refs. 9 through 12, 14, and 15); and (3) physical mapping, whereby the cloned DNA segments were shown to be large enough to contain the prochymosin gene and, when specifically cut with appropriate DNA cutting enzymes and run on gels to separate the resulting DNA fragments by size, were shown to yield the pattern of DNA fragments expected from the prochymosin gene (Refs. 9 through 12, and 14 through 16).

The published evidence establishes that the new host organisms are able to use the prochymosin gene to produce prochymosin that has the same molecular weight as the prochymosin found in calf rennet (Refs. 12, 14, and 15 through 18). This evidence also establishes that the prochymosin that is produced (cloned prochymosin) can be cleaved into chymosin (cloned chymosin) that has the same molecular weight and the same functional activity as chymosin found in calf rennet (Refs. 11, 12, and 15 through 19).

The molecular weights of prochymosin and chymosin were assayed, using sodium dodecyl sulfate polyacrylamide gel electrophoresis, a technique that allows determination of the comparative molecular weight of proteins based on their rate of migration through the gel. Cloned prochymosin was found to migrate through these gels at the same rate as the prochymosin derived from calves (Refs. 12, 14, and 15 through 18). Cloned chymosin was found to migrate through these gels at the same rate as the chymosin found in rennet (Refs. 11, 12 and 15 through 19).

The functional activity of chymosin that was measured was milk-clotting activity. Cloned chymosin was found to clot milk at the same rate as the chymosin in rennet under various temperatures, salt concentrations, and pH conditions (Refs. 11, 12, 14, 15 through 18, 20, and 21).

One safety concern raised by cloning is whether extraneous DNA, particularly DNA flanking the gene of interest which could potentially encode extraneous harmful proteins, may be cloned along with the gene of interest (i.e., the prochymosin gene).

As a matter of current good manufacturing practice, manufacturers using recombinant DNA technology must be sure that they have not inadvertently cloned extraneous protein-encoding DNA along with the prochymosin gene. Such assurance can come from reviewing the details of the cloning steps, such as the origin and sequence of all the DNA fragments, and from full characterization of the final genetic constructs via techniques such as DNA sequencing. The agency finds that the petition of Gist-brocades, Inc., contains information demonstrating that the firm conducted these steps and that the strain does not include extraneous protein-encoding DNA along with the prochymosin gene.

Furthermore, the amended regulation stipulates that the substance being affirmed as GRAS is one that is produced using a production strain that is nontoxigenic. (See § 184.1685(a)(3).) If the cloned DNA encodes a harmful substance that could render the enzyme preparation unsafe, the production strain would be considered toxigenic, and the substance produced would not be GRAS under § 184.1865(a)(3). Therefore, the agency finds that there is no basis for concern that the safety of the chymosin preparation will be compromised by contaminating proteins encoded by extraneous uncharacterized DNA cloned along with the prochymosin gene.

Based on the fact that published information demonstrates that chymosin produced from the cloned prochymosin gene has the same molecular weight and the same functional activity as the chymosin derived from calves, FDA concludes that the chymosin enzyme in this chymosin preparation is the same as the chymosin enzyme in calf rennet. Therefore, FDA concludes that the chymosin enzyme in this chymosin preparation is as safe as the chymosin enzyme in rennet.

C. Sources of Impurities

Enzyme preparations used in food-processing are not chemically pure but contain extraneous source (cellular and processing) materials. The nature and amounts of these materials in the finished enzyme preparation depend on the organism from which the enzyme preparation is produced (the source or production organism), the fermentation materials and methods used to grow the production organism, and the materials and methods used to generate the finished enzyme preparation.

Both the source material and the manufacturing methods for producing the chymosin preparation differ from those used to produce animal rennet. Therefore, the impurities in the chymosin preparation will differ from those in rennet. The question thus is whether the source material or manufacturing methods for the chymosin preparation will introduce impurities that would raise concerns about the safety of the preparation.

1. Processing Steps

Researchers in several laboratories have published papers describing methods that they used for producing chymosin preparation from microorganisms containing the calf prochymosin gene (Refs. 11, 12, 14 through 19, and 22). The enzyme that is the subject of this petition is secreted from the production organism during fermentation and therefore, is an extracellular enzyme product. Thus, it is not necessary to disrupt the cells to recover the enzyme. Extracellular enzymes account for approximately three-fourths of the market for fermentation-derived enzymes, and the techniques used in their production and processing are well-known (Ref. 23). The processing methods described by Gist-brocades, Inc., in this petition do not differ in any significant way from the published methods used to produce extracellular enzymes generally. The

key steps described by Gist-brocades, Inc., are summarized below.

K. marxianus var. *lactis* is grown in a liquid nutrient medium. The aerobic growth phase of the fermentation step is monitored and allowed to continue until laboratory analyses show that the maximum production of the desired enzyme activity has been achieved. The fermentation is stopped by lowering the pH of the fermentation broth to 2 by adding sulfuric acid and sodium benzoate. The low pH induces the conversion (autocatalysis) of prochymosin to chymosin. The cell material is separated from the chymosin-containing fraction of the broth by filtration. The supernatant is then sterilized by filtration and subjected to ultrafiltration to concentrate the chymosin to the desired enzymatic activity. The chymosin preparation is formulated with sodium chloride and stabilizers (Ref. 24).

FDA finds that the Gist-brocades manufacturing method does not require the use of any processing materials that are not GRAS or not approved food additives. Accordingly, in the amended regulation, the agency specifies that the substance being affirmed as GRAS is one that is produced using only processing materials that are GRAS substances or food additives approved for use in this type of process.

Therefore, the agency concludes that the manufacturing steps will not introduce impurities into the enzyme preparation that will adversely affect the safety of the chymosin preparation.

2. Production Organism

The source material for the chymosin in the chymosin preparation that is the subject of the final rule set forth below is the production organism *K. marxianus* var. *lactis*. The currently accepted classification of the organism is *K. marxianus* (Hansen) van der Walt variety *lactis* (Dombrowski) Johannsen et van der Walt (Refs. 25 through 27). In the regulation, this organism will be referred to as *K. marxianus* var. *lactis*. Previously, FDA reviewed the safety of the use of *K. marxianus* var. *lactis* (previously named *K. lactis*) as a source of lactase enzyme preparation and concluded that the organism is nonpathogenic and nontoxigenic, and thus, generally recognized as safe (21 CFR 184.1388).

The strain of *K. marxianus* var. *lactis* used in the production of the chymosin preparation that is the subject of the amendment of the regulation was genetically modified by the introduction of the prochymosin gene. The petitioner conducted several studies to determine whether the genetic modification of *K. marxianus* var. *lactis* to produce chymosin altered the safety of the organism; these studies are corroborative evidence of the organism's safety. In one study, the production organism was tested for pathogenicity in mice; this study confirmed that the genetic modification of the organism did not render the organism pathogenic. As additional corroborative evidence of the safety of the chymosin preparation, the petitioner submitted five unpublished in vivo toxicity studies in rats fed either the Gist-brocades chymosin preparation or cheese produced with this chymosin preparation. The studies were: (1) An acute oral toxicity study of the Gist-brocades chymosin preparation; (2) a short-term oral toxicity study with cheese made with the chymosin preparation added to the feed; (3) a 91-day subchronic oral toxicity study of the chymosin preparation; (4) a 91-day subchronic feeding study with cheese made using the chymosin preparation; and (5) a passive cutaneous anaphylaxis of the chymosin preparation. In these five studies, no significant adverse effects were observed in rats fed either the chymosin preparation or cheese manufactured with the chymosin preparation.

Some *K. marxianus* var. *lactis* strains, such as those that are used by Gist-brocades, Inc., and others to produce chymosin preparation, contain marker genes that encode resistance to clinically useful antibiotics. Such genes could potentially be transferred to other microorganisms with which the production strain or its DNA comes into contact. However, as previously described, the procedure used to manufacture the chymosin preparation eliminates most cellular material, reducing the likelihood of DNA contamination of the chymosin preparation. Additionally, the acid treatment step in the manufacturing process inactivates residual cells and degrades residual DNA, including marker genes, that remain in the enzyme preparation (Ref. 28).

As corroborative evidence that the enzyme preparation does not contain transformable DNA (that is, DNA that a microorganism can take up from its surroundings and functionally incorporate into its own DNA), Gist-brocades, Inc., submitted data from unpublished transformation experiments. In the transformation assay, bacterial cells were mixed with DNA under optimized conditions and assayed to see if they picked up the antibiotic resistance encoded by the DNA. In the case of the Gist-brocades enzyme preparation, cells mixed with the preparation did not become antibiotic-resistant (Ref. 29). Based on the foregoing evidence, FDA concludes that chymosin preparation manufactured in conformity with § 184.1685(a)(3) will not contain DNA encoding resistance to antibiotics at levels that would produce any safety concern.

Having considered the evidence concerning the processing steps and the production organism, FDA concludes that *K. marxianus* var. *lactis* is safe for use as a source of food-grade chymosin preparations, and that impurities resulting from its use in the production of the chymosin preparation will not affect the safety of that preparation.

IV. Specifications

The agency finds that, because the principal active ingredient of the chymosin preparation and rennet are the same, and because the impurities in chymosin preparation do not provide any basis for concern about the safe use of the preparation, the general requirements for enzyme preparations in § 184.1685(b) are adequate for defining minimum criteria for a food-grade chymosin preparation derived from *K marxianus* var. *lactis*.

V. Conclusion

The agency has evaluated all available information, and finds, based on the published and corroborative evidence discussed above, that the active principal ingredient in the chymosin preparation is the same as that in rennet, and that when the preparation is manufactured in accordance with § 184.1685(a)(3), the source organism and manufacturing process will not introduce impurities into the preparation that may render the preparation unsafe. Therefore, the agency concludes, based upon scientific procedures, that the chymosin preparation derived by fermentation from *K. marxianus* var. *lactis* and described in the regulation (21 CFR 184.1685(a)(3)) is GRAS for use as a replacement for rennet.

VI. Environmental Effects

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Economic Effects

In accordance with the Regulatory Flexibility Act, the agency considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action.

In accordance with Executive Order 12291, FDA has analyzed the potential economic effects of this final rule. The agency has determined that the rule is not a major rule as defined by the Executive Order.

The agency's finding of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

VIII. References

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 am. and 4 p.m., Monday through Friday.

1. Foltmann, B., "Prochymosin and Chymosin (Prorennin and Rennin)," Methods in Enzymology, 19:421–436, 1970.

2. Burgess, K., M. and Shaw, "Dairy," Industrial Enzymology, Godfrey, T., and J. Reichelt, editors, The Nature Press, New York, pp. 260–265, 1983.

3. **Federal Register**, 48 FR 51151, November 7, 1983.

4. **Federal Register**, 55 FR 10932, March 23, 1990.

5. Foltmann, B. et al., "The Primary Structure of Calf Chymosin," Journal of Biological Chemistry, 254:8447–8451, 1979.

6. Murray, K., "Genetic Engineering and Its Applications," Basic Biotechnology, Bu'Lock, J., and B. Kristiansen, editors, Academic Press, London, pp. 483–508, 1987.

7. Watson, J. D. et al., "Molecular Biology of the Gene," Benjamin/Cummings Publishing Co., Inc., Menlo Park, CA, pp. 65–94, 202–213, 1987.

8. Harris, T. J. R. et al., "Molecular Cloning and Nucleotide Sequence of cDNA Coding for Calf Preprochymosin," Nucleic Acids Research, 10:2177–2187, 1982.

9. Hidaka, M. et al., "Cloning and Structural Analysis of the Calf Prochymosin Gene," Gene, 43:197–203, 1986.

10. Moir, D. et al., "Molecular Cloning and Characterization of Double-stranded cDNA Coding for Bovine Chymosin," Gene, 19:127–138, 1982.

11. Cullen, D. et al., "Controlled expression and secretion of bovine chymosin in *Aspergillus nidulans*," Bio/Technology, 5:369–376, 1987.

12. Emtage, J. S. et al., "Synthesis of Calf Prochymosin (Prorennin) in *Escherichia coli*," Proceedings of the National Academy of Sciences, 80:3671–3675, 1983.

13. Hollenberg, C. P. et al., International Patent Application, "Cloning System for *Kluyveromyces* Species," No. WO 83/04050, pp. 1–41, 1983.

14. Goff, C. G. et al., "Expression of Calf Prochymosin in *Saccharomyces cerevisiae*," Gene, 27:35–46, 1984.

15. McCaman, M. T., W. H. Andrews, and J. G. Files, "Enzymatic Properties and Processing of Bovine Prochymosin Synthesized in *Escherichia coli*," Journal of Biotechnology, 2:177–190, 1985.

16. Mellor, J. et al., "Efficient Synthesis of Enzymatically Active Calf Chymosin in *Saccharomyces cerevisiae*," Gene, 24:1–14, 1983.

17. Kawaguchi, Y. et al., "Production of Chymosin in *Escherichia coli* Cells and its Enzymatic Properties," Agricultural and Biological Chemistry, 51:1871–1877, 1987.

18. Marston, F. A. O. et al., "Purification of Calf Prochymosin (Prorennin) in *Escherichia coli*," Bio/Technology, 2:800–804, 1984.

19. Van den Berg, J. A. et al., "*Kluyveromyces* as a Host for Heterologous Gene Expression: Expression and Secretion of Prochymosin," Bio/Technology, 8:135–139, 1990.

20. Hicks, C. L., J. O'Leary, and J. Bucy, "Use of Recombinant Chymosin in the Manufacture of Cheddar and Colby Cheese," Journal of Dairy Science, 71:1127–1131, 1988.

21. O'Sullivan, M., and P. F. Fox, "Evaluation of Microbial Chymosin from Genetically Engineered *Kluyveromyces lactis*," Food Biotechnology, 5:19–32, 1991.

22. Van den Berg, J. A. et al., European Patent Application, "Kluyveromyces as a Host Strain," No. 88201632.2, Publication No. EP–O 301/670–A1, pp. 1–26, 1988.

23. Frost, G. M., and D. A. Moss, "Production of Enzymes by Fermentation," Biotechnology, vol. 7A, Rehm, H. J., and G. Reed, editors, VCH, New York, pp. 72–76, 1987.

24. Brummer, W., and G. Gunzer, "Laboratory Techniques of Enzyme Recovery," Biotechnology, vol. 7A, Rehm, H. J., and G. Reed, editors, VCH, New York, pp. 217–219 and 273, 1987.

25. Dombrowski, W., "Die Hefen in Milch und Milchproducken", in *Centralblatt fur Bacteriologie, Parasitenkunde und Infektionskrankheiten*, Uhlworn, O., editor, pp. 345–403, 1910.

26. Van der Walt, J. P., "Genus 8 *Kluyveromyces* van de Walt emend. van der Walt," The Yeasts. A Taxonomic Study, 2d ed., Lodder, J., editor, North Holland Publishing Co., Amsterdam, pp. 316–327, 345–352, 1970.

27. Van der Walt, J. P., and E. Johannsen, "Genus 13. *Kluyveromyces* van der Walt emend. van der Walt," The Yeasts: A Taxonomic Study, 3d revised and enlarged ed., Kreger-van Rij, N. J. W., editor, Elsevier Science Publishers B. V., Amsterdam, pp. 224–251, 1984.

28. Lehninger, A. L., Biochemistry, Worth Publishers, New York, p. 256, 1970.

29. Petition 9G0349.

List of Subjects in 21 CFR Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 184.1685 is amended by adding new paragraph (a)(3) to read as follows:

§ 184.1685 Rennet (animal-derived) and chymosin preparation (fermentation-derived).

(a) * * *

(3) Chymosin preparation is a clear solution containing the active enzyme chymosin (E.C. 3.4.23.4). It is derived, via fermentation, from a nonpathogenic and nontoxigenic strain of *Kluyveromyces marxianus* variety *lactis*, containing the prochymosin gene. The prochymosin is secreted by cells into fermentation broth and converted to chymosin by acid treatment. All materials used in the processing and formulating of chymosin must be either generally recognized as safe (GRAS), or be food additives that have been approved by the Food and Drug Administration for this use.

* * * * *

Dated: February 13, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92–4226 Filed 2–24–92; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Parts 200, 201, and 202

[Docket No. R–92–1496; FR–2623–C–03]

Introduction; Title I Property Improvement and Manufactured Home Loans; Approval of Lending Institutions; Reform of the Title I Program; Corrections

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule; corrections.

SUMMARY: This document corrects certain editorial and typographical errors in the Department's final rule which was published in the **Federal Register** on October 18, 1991 (56 FR 52414). The October 18, 1991 final rule amended 24 CFR parts 200, 201, and 202 with regard to the insurance of lenders against losses sustained as a result of borrower defaults on property improvement and manufactured home loans.

EFFECTIVE DATE: November 18, 1991.

FOR FURTHER INFORMATION CONTACT: Robert J. Coyle, Director, Title I Insurance Division, room 9158, 451 Seventh Street SW., Washington, DC 20410. Telephone number (202) 708–2880, or (202) 708–4594 (TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: On October 18, 1991 (56 FR 52414), the Department published a final rule implementing major changes to reform the title I property improvement and manufactured home loan programs. The effective date of the final rule was November 18, 1991.

Since the final rule was published, the Department has discovered certain typographical and editorial errors in the amendatory instructions for several of the amendments made to 24 CFR part 201, and in §§ 201.26(a)(6)(i), 201.50(a), and 201.54(c)(1). This document corrects these errors.

In addition to these errors, the final rule also incorrectly cited the OMB control number for the information collection requirements in §§ 202.1, 202.3, 202.5, and 202.6 in the final rule. The OMB control number was incorrectly given as "2502–0328". The correct number is "2502–0017." This document makes this correction as well.

The preamble to the final rule, which provides background information on the program reforms, also contained a number of typographical and editorial errors. The Department discovered six typographical and editorial errors in the preamble, which the Department believes are important to identify and correct because these errors may be misleading as to the intended meaning of certain of the regulatory provisions. These preamble errors are corrected by this document.

Accordingly, the following corrections are made to FR Doc. 91–24721, published on October 18, 1991 at 56 FR 52414.

In the preamble, the following corrections are made:

1. On page 52414, in numbered paragraph 2 in both the first and second columns, the apostrophe after the word "dealers" is replaced by a comma.

2. On page 52414, in numbered paragraph 3 in both the first and second columns, the comma after the word "dealers" (the second time this word appears), is replaced by an apostrophe.

3. On page 52415, in the first full paragraph in the first column, the phrase "applying for approval" in the second sentence is replaced by "approved." This change is made to agree with the clear language on applicability of the net worth and line of credit requirements in the text of the regulation.

4. On page 52416, in the first full paragraph in the second column, the last sentence is corrected to read "Therefore, partnerships will not be eligible to be Title I lending institutions, unless they can show that they are permanent organizations having succession."

5. On page 52423, in the first full paragraph in the third column, the phrase "dealer and the borrower" in the third sentence is replaced by "dealer or the borrower".

6. On page 52425, in the third column, the word "purchases" in the last line of the manufacturer's certification is replaced by "purchaser".

In the regulatory text, the following corrections are made:

PART 201—[CORRECTED]

7. On page 52428, in the first column, the amendatory instruction 4 should read:

"4. Section 201.2 is amended by removing paragraph (ii); by redesignating paragraphs (g) through (o) as paragraphs (h) through (p); by redesignating paragraphs (p) through (hh) as paragraphs (r) through (jj); by redesignating paragraphs (jj) through (ll) as paragraphs (kk) through (mm); by adding new paragraphs (g) and (q); and by revising paragraph (c) and newly redesignated paragraphs (h), (i), (o), (r), (ll)(2), and (mm), to read as follows:"

8. On page 52431, in the second column, the amendatory instruction 14 should read:

"14. Section 201.22 is amended by removing paragraph (a)(5); by redesignating paragraphs (a) (3), (4), and (6) as paragraphs (a) (4), (5), and (10), respectively; by adding new paragraphs (a) (3), (6), (7), (8), and (9); and by revising paragraphs (a)(2) and (b), to read as follows:"

9. On page 52432, in the first column, the amendatory instruction 16 should read:

"16. Section 201.25 is amended by removing paragraph (b)(2)(v); by revising paragraphs (b)(1)(iii)–(v), (b)(2)(ii)–(iv), and (c)(5), (8), (10), and (11); and by adding new paragraphs (b)(1)(vi), (c)(12), and (d), to read as follows:"

10. On page 52432, in the second column, the amendatory instruction 17 should read:

"17. Section 201.26 is amended by revising paragraphs (a)(1), (2) and (5)(ii); by redesignating paragraph (a)(6) as (a)(7); by removing paragraphs (b)(8) and (10); by redesignating paragraph (b)(9) as (b)(8); and by revising paragraphs (b)(2)(iii) and (iv), (3)(i), (iii), (v), and (vi), (4), (6), and (7); and by adding new paragraphs (a)(6) and (b)(3)(vii), to read as follows:"

11. On page 52432, in the third column, § 201.26(a)(6)(i) is corrected to read as follows:

§ 201.26 Conditions for loan disbursement.

(a) * * *

(6) * * *

(i) States that the loan will be insured by HUD and describes the actions the Secretary may take to recover the debt if the borrower defaults on the loan and an insurance claim is paid;

* * * * *

§ 201.50 [Corrected]

12. On page 52434, in the third column, § 201.50 is corrected by removing "(1)" following the heading of paragraph (a).

13. On page 52434, in the third column, § 201.54(c)(1) is corrected to read as follows:

§ 201.54 Insurance claim procedure.

* * * * *

(c) *Resubmitted and supplemental claims.* (1) Any insurance claim which is resubmitted with an appeal of a claim denial or a request for a waiver of the regulations in accordance with § 201.5(b) shall be filed within six months after the date of the claim denial.

* * * * *

PART 202—[CORRECTED]

14. On page 52436, in the second column, the OMB approval number at the end of § 202.1 is corrected to read as follows:

§ 202.1 Approval of financial institutions.

* * * * *

(Approved by the Office of Management and Budget under control number 2502–0017.)

15. On page 52437, in the first column, the OMB approval number at the end of § 202.3 is corrected to read as follows:

§ 202.3 General approval requirements.

* * * * *

(Approved by the Office of Management and Budget under control number 2502–0017.)

16. On page 52437, in the second column, the OMB approval number at the end of § 202.5 is corrected to read as follows:

§ 202.5 Requirements for nonsupervised lenders.

* * * * *

(Approved by the Office of Management and Budget under control number 2502–0017.)

17. On page 52437, in the third column, the OMB approval number at the end of § 202.6 is corrected to read as follows:

§ 202.6 Requirements for loan correspondents.

* * * * *

(Approved by the Office of Management and Budget under control number 2502–0017.)

Dated: February 18, 1992.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 92–4186 Filed 2–24–92; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 916

Kansas; State Program Provisions and Amendments Disapproved

CFR Correction

In title 30 of the Code of Federal Regulations, part 700 to end, revised as of July 1, 1991, on pages 489 and 490, § 916.12 appears twice. When § 916.12 was revised at 53 FR 39470, October 7, 1988, the superseded text was incorrectly retained in the volume.

Therefore, the second version of § 916.12 appearing on pages 489 and 490 is removed.

BILLING CODE 1505–01–D

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[File No. E–89–297, FCC No. 92–36]

Interchange Common Carrier Services

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This Memorandum Opinion and Order denies in part and dismisses in part AT&T Communications' formal complaint filed against MCI Telecommunications Corporation alleging that MCI provides common carrier telecommunications services to customers at rates, and on terms and conditions, that are not filed or contained in interstate tariffs, in violation of section 203 of the Communications Act. The effect of this order will be to protect customers' reliance interests in Commission rules and to benefit the public by ensuring that fundamental Commission's rules are not amended in a two-party adjudicatory proceeding.

EFFECTIVE DATE: March 26, 1992.

FOR FURTHER INFORMATION CONTACT: Gary Phillips, (202) 632–4047, or Andy Lachance, (202) 632–4047, Policy and Program Planning Division, Common Carrier Bureau.

SUPPLEMENTARY INFORMATION: On August 7, 1989, AT&T Communications filed a formal complaint with this Commission pursuant to sections 206 and 208 of the Communications Act alleging that MCI Telecommunications Corporation provides common carrier telecommunications services to several customers at rates, and on terms and conditions, that are not filed or contained in interstate tariffs, in violation of section 203 of the Act.

We now deny AT&T's complaint in part and dismiss it in part. We deny AT&T's complaint insofar as it claims that MCI is liable for damages because its practice of providing service off-tariff violates section 203 of the Act. Any off-tariff service offerings by MCI have been made pursuant to rules promulgated by the FCC in orders that were not challenged on review and have long since become final. We will not award damages against MCI based simply on allegations made years later that the rules to which MCI conformed its conduct are beyond our authority to adopt.

We also dismiss AT&T's complaint insofar as it seeks prospective relief enjoining MCI from providing off-tariff services. This claim, while nominally stated in terms of a request for relief against MCI, is in practical effect a challenge to the Commission's previously adopted and effective forbearance rule.

The Commission's forbearance rule was adopted in a notice and comment rulemaking proceeding and has been in place for almost ten years. This rule represents one of the cornerstones of our regulation of the long-distance industry. Any change in this fundamental policy would have a significant impact on a broad range of customers and providers of telecommunications services across the nation. It would be inappropriate for us to consider a modification or repeal of this policy, with so potentially widespread an impact, in the context of a two-party adjudicatory proceeding, as opposed to a rulemaking proceeding. In a rulemaking, all interested parties will have the opportunity to comment. In addition, a rulemaking proceeding will permit us to address our forbearance rule as it applies to all nondominant carriers, and to consider and implement any changes that we may make to it on an industry-wide basis. Given the fundamental importance of these matters, the coordinated and comprehensive approach made possible by a rulemaking will reduce industry uncertainty, while ensuring the smoothest possible transition to any new rules that may be necessary.

I. Ex Parte Rules

In light of the interrelationship between this proceeding and the Notice of Proposed Rulemaking we adopt today, to the extent this complaint proceeding remains pending through a petition for reconsideration or appeal of this order, the proceeding will henceforth be deemed a non-restricted proceeding under the Commission's *ex parte* rules. Ex parte presentations will be permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in Commission Rules.

II. Ordering Clause

For the reasons set forth above, pursuant to 47 U.S.C. 208, *It is Ordered*, That AT&T's above-referenced complaint is denied in part and dismissed in part.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 92–4064 Filed 2–24–92; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 90–173; RM–7171]

Radio Broadcasting Services; Doolittle, MO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 283A to Doolittle, Missouri, as that community's first local service in response to a petition filed by Howard Smith. See 55 FR 12870, April 6, 1990. The coordinates for Channel 283A are 37–55–01 and 91–55–18. There is a site restriction 4.4 kilometers (2.8 miles)