(1) The manufacture of a finished product for the free-choice administration of a new animal drug. Such an approval will not provide a basis upon which an application can be approved under section 512(m) of the act; or

(2) The manufacture of a Type A medicated article for use in the subsequent manufacture of a free-choice medicated feed. The approved NADA will provide a basis upon which an application can be approved under section 512(m) of the act. Data for a specific free-choice product may, if desired, be generated and submitted to the Food and Drug Administration by the manufacturer of the free-choice feed in the form of a master file which can be referenced in the NADA or supplemental NADA submitted by the new animal drug sponsor.

(d) Approval of the NADA or supplemental NADA submitted under paragraph (c) of this section will be reflected in a regulation in part 558 of this chapter published under section 512(i) of the act. The regulation will either state the formulation of the approved free-choice product or specify the specific free-choice administration products in which the drug is approved for use. If the approval is for a Type A medicated article, the regulation in part 558 of this chapter will indicate that each use of the Type A medicated article in a free-choice product must be the subject of an approved supplemental NADA.

(e) An application submitted under section 512(m) of the act to provide for manufacture of a specific free-choice feed from an approved Type A medicated article will be approved if, in addition to the information required by the medicated feed application, it includes a reference to the exact formula of the product to be manufactured as follows:

(1) The formula is the same as the one published in the new animal drug regulations; or

(2) The data in a master file have been referenced in an NADA or supplemental NADA; and

(3) Use of the Type A medicated article in the specific formulation has been approved on the basis that:

(i) The formula is the same as the one for which acceptable data have been submitted in a master file by the medicated feed applicant; or

(ii) The medicated feed applicant has written authority to reference a master file that has acceptable data for the formula in question.

(Approved by the Office of Management and Budget under control number 0910–0205)

[51 FR 19827, June 3, 1986]

Subpart F—Animal Use Exemptions From Certification and Labeling Requirements

§ 510.515 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Animal feeds that bear or contain penicillin, chlortetracycline, feed grade zinc bacitracin, and bacitracin methylene disalicylate, with or without added suitable nutritive ingredients are exempt from the certification requirements of section 512 of the act provided they are the subject of and in compliance with regulations for their use in this subchapter E, part 558 of this chapter, or any one of the paragraphs of this section:

(a) Where indicated in paragraph (b) of this section it is manufactured with or without one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.

(2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.

(3) 3-Nitro-4-hydroxyphenylarsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent except in chicken or turkey feed which shall contain not less than 0.0025 percent and not more than 0.005 percent.

(b) It is intended for use in any one of the following conditions set forth in this paragraph:

(1) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), infectious sinusitis, and blue comb (nonspecific infectious enteritis) in poultry and/or bacterial swine enteritis; its labeling bears adequate directions and warnings for such use; and it contains, per ton of

feed, the equivalent of 100 grams of penicillin. When intended for uses specified in this paragraph, it may also contain, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(2) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection) and infectious sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt or para-aminobenzoic acid.

(3)–(29) [Reserved]

(c) It is intended for use as follows:

Product	Species	Use levels	Indications for use
1. Nicarbazin	Chickens	0.01 to 0.02 percent	For use in the prevention of outbreaks of coccidiosis in poultry flocks; growth promotion and feed efficiency.
	...do	2.4 to 50 g/ton	
2. Nicarbazin	...do	0.01 to 0.02 percent	Do.
Bacitracin methylene disalicylate.	...do	4 to 50 g/ton.	
3. Nicarbazin	...do	0.01 to 0.02 percent	For use as an aid in the prevention of coccidiosis in poultry flocks; growth promotion and feed efficiency; improving pigmentation.
Bacitracin methylene disalicylate.	...do	4 to 50 g/ton.	
3-Nitro-4-hydroxyphenylarsonic acid.	...do	0.0025 to 0.005 percent.	
4. Nicarbazin	...do	0.01 to 0.02 percent	Do.
Procaine penicillin	...do	2.4 to 50 g/ton.	
3-Nitro-4-hydroxyphenylarsonic acid.	...do	0.0025 to 0.005 percent.	
5. Chlortetracycline	Swine	10 to 50 g/ton	Enhancement of growth and feed efficiency.
Arsanilic acid	...do	0.005 to 0.01 percent.	

[41 FR 8299, Feb. 25, 1976, as amended at 41 FR 11011, Mar. 15, 1976; 42 FR 18614, Apr. 8, 1977; 47 FR 42102, Sept. 24, 1982; 47 FR 51563, Nov. 16, 1982; 56 FR 41912, Aug. 23, 1991; 58 FR 30119, May 26, 1993; 61 FR 35950, July 9, 1996]

Subpart G—Sponsors of Approved Applications

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

(a) Section 512(i) of the act requires publication of names and addresses of sponsors of approved applications for new animal drugs.

(b) In this section each name and address is identified by a numerical drug labeler code. The labeler codes identify the sponsors of the new animal drug applications associated with the regulations published pursuant to section 512(i) of the act. The codes appear in the appropriate regulations and serve as a reference to the names and addresses listed in this section. The drug labeler code is established pursuant to section 510 of the act.

(c) The names, addresses, and drug labeler codes of sponsors of approved new animal drug applications are as follows:

(1) ALPHABETICAL LISTING OF SPONSORS

Firm name and address	Drug labeler code
Abbott Laboratories, North Chicago, IL 60064	000074
ADM Animal Health & Nutrition Division, 1000 North 30th St., Box 1C, Quincy, IL 62305–3115	017519
Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	024174
Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503	057561
Agri-Tech, Inc., 4722 Broadway, Kansas City, MO 64112	017762
Akey, Inc., P.O. Box 607, Lewisburg, OH 45338	017790
Akzo Nobel Surface Chemistry AB, Box 851, S–44485 Stenungsund, Sweden	063765
Alaco, Inc., 1500 North Wilmot Rd., suite 290–C, Tucson, AZ 85712	064146
Albion Laboratories, Inc., 101 North Main, Clearfield, UT 84015	011485
Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024	046573
Alstoe, Ltd., Animal Health, Granary Chambers, 37–39 Burton St., Melton Mowbray, Leicestershire LE13 1AF, England	062408
Altana Inc., 60 Baylis Rd., Melville, NY 11747	025463