Issued in Renton, Washington, on February 20, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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FEDERAL TRADE COMMISSION

16 CFR Part 304

Rules and Regulations Under the Hobby Protection Act

AGENCY: Federal Trade Commission.

ACTION: Confirmation of rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') has completed its regulatory review of the Rules and Regulations Issued Under the Hobby Protection Act (''rule''). The rule regulates the marking of imitation political and numismatic items. Pursuant to its regulatory review, the Commission concludes that the rule continues to be valuable both to consumers and businesses.

DATES: This action is effective as of March 3, 2004.

FOR FURTHER INFORMATION CONTACT: Janice Podoll Frankle, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC 20580; (202) 326–3022.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Commission has determined, as part of its oversight responsibilities, to review its rules and guides periodically to seek information about their costs and benefits and their regulatory and economic impact. The information obtained assists the Commission in identifying rules and guides that warrant modification or rescission.

II. Background

On November 29, 1973, Congress passed the Hobby Protection Act (''Act''), 15 U.S.C. 2101–06. The Act requires manufacturers and importers of ''imitation political items'' [1] to mark ''plainly and permanently'' such items with the ''calendar year'' such items were manufactured. *Id.* at 2101(a). The Act also requires manufacturers and importers of ''imitation numismatic items'' [2] to mark ''plainly and permanently'' such items with the word ''copy.'' *Id.* at 2101(b). The Act further directs the Commission to promulgate regulations for determining the ''manner and form'' that imitation political items and imitation numismatic items are to be permanently marked with the calendar year of manufacture or the word ''copy.'' *Id.* at 2101(c) .

Pursuant to the Act, in 1975 the Commission issued rules and regulations under the Hobby Protection Act, 16 CFR part 304. The rule tracks the definitions of terms used in the Act and implements the Act's ''plain and permanent'' marking requirements by establishing the sizes and dimensions of the letters and numerals to be used, the location of the marking on the item, and how to mark incusable and nonincusable items.[3] In 1988, the rule was amended to provide additional guidance on the minimum size of letters for the word ''copy'' as a proportion of the diameter of coin reproductions.[4] 53 FR 38942 (October 4, 1988).

On March 3, 2003, the Commission published a **Federal Register** notice (''FRN'') seeking comment on the rule as part of the Commission's ongoing project to review periodically its rules and guides to determine their current effectiveness and impact (68 FR 9856). This FRN sought comment on the costs and benefits of the rule, what changes in the rule would increase its benefits to purchasers and how those changes would affect compliance costs, and whether technological or marketplace changes have affected the rule.

The comments submitted in response to the FRN generally expressed continuing support for the rule, indicating that it has created a level playing field among competitors. The vast majority of comments proposed that the Commission expand the rule to address problems involving the selling (passing off) as originals of reproductions of antiques and collectibles not covered by the Act and rule.[5] The Commission, however, does not have authority under the Act to amend the rule as requested. In addition, existing laws and informational material disseminated by various collecting clubs address many of the concerns raised by these comments.

III. Regulatory Review Comments

The Commission received 350 comments in response to its FRN.[6] Approximately 248 comments were letters and e-mails from individual collectors who advocated expanding the rule's coverage to all antiques and collectibles. The vast majority of these were form letters from individual collectors. Of the remainder, eight were from national trade associations and collector groups,[7] three were from hobby publications,[8] and the remaining were from dealers,[9] State and local trade associations and local chapters of national groups,[10] and antique appraisers.[11]

The Commission discusses the comments in two sections. In section A, the Commission analyzes the comments relating to political and numismatic products. (''covered products''). In section B, the Commission discusses the comments on expanding the Act and rule to cover all antiques and collectibles.

[1] An imitation political item is ''an item which purports to be, but in fact is not, an original political item, or which is a reproduction, copy, or counterfeit of an original political item.'' 15 U.S.C. 2106(2). The Act defines original political items as being any political button, poster, literature, sticker or any advertisement produced for use in any political cause. *Id.* at 2106(1). The political items dealers sell include presidential, local election, and cause-type buttons, pins, posters, tie clasps, cuff links, mugs, photos, inauguration invitations, marshal's badges, medals, ribbons and the like.

[2] An imitation numismatic item is ''an item which purports to be, but in fact is not, an original numismatic item or which is a reproduction, copy, or counterfeit of an original numismatic item.'' 15 U.S.C. 2106(4). The Act defines original numismatic items to include coins, tokens, paper money, and commemorative medals that have been part of a coinage or issue used in exchange or used to commemorate a person or event. *Id.* at 2106(3).

[3] Incusable items are those that can be impressed with a stamp.

[4] Prior to the amendment, if a coin were too small to comply with the minimum letter size requirements, the manufacturer or importer individually had to request from the Commission a variance from those requirements. Because imitation miniature coins were becoming more common, the Commission determined that it was in the public interest to allow the placing of the word ''copy'' on miniature imitation coins in sizes that could be reduced proportionately with the size of the item.

[5] Although the comments overwhelmingly supported expansion of the Act and rule, they did not specifically respond to all of the questions posed in the March 2003 FRN.

[6] The comments are cited in this notice by the name of the commenter. All rule review comments are on the public record and are available for public inspection in the Consumer Response Center, Room 130, Federal Trade Commission, 6th and Pennsylvania Ave., NW., Washington, DC, from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

[7] National Association of Collectors and Association of Collecting Clubs (NAC); Wagner and Griswold Society; Custard Glass Collectors Society; Toy Train Collectors Association; Hamm's Club, Inc.; Casino Chips and Gaming Tokens Collectors Club; National Association of Milk Bottle Collectors; and National Insulator Association.

[8] Antique & Collectors Reproduction News; Coin World; and Kettle 'n Cookware.

[9] *E.g.,* Americana Resources, Inc.

[10] Antique Dealers Association of Berks County, Inc.; The Questers; Michigan Hunting & Fishing License Collectors Club; American Political Items Collectors, National Capital Chapter; and Apple Valley Bottle Collectors.

[11] *E.g.,* Donald Hoffman.

A. Comments Relating to Covered Products

1. Support for the Rule

As previously discussed, the Act and rule's scope are limited to imitation political and numismatic items. The comments uniformly stated that there is a continuing need for the rule and that it has been successful in protecting consumers from the passing off of reproductions of the covered items.[12] In explaining the continuing need for the Act and rule, one commenter stated that the coin collecting hobby is currently experiencing a renaissance, due in large part to the 50 state quarters program that the U.S. Mint launched in 1999.[13] A dealer in political memorabilia on the Internet stated that most collectors of political items feel comfortable for one reason—the Hobby Protection Act.[14]

2. Proposed Amendments Regarding Covered Products

a. Require Replicas To Be Marked ''Copy'' Regardless of the Metal Content

One commenter stated that some manufacturers ''skirt'' the rule by adding a hallmark or varying the metal so as to claim that the item is not an ''exact'' replica.[15] The commenter asserted that the consuming public may not be able to discern the immediate difference in metal content in a coin that is in every other respect an exact duplicate of the rare coin. According to the commenter, this problem is exacerbated when the coin is sold in the secondary market, where it is often perceived and sold as a genuine coin. The commenter suggested requiring any replica that duplicates the genuine design elements, legends and denomination markings to be marked ''copy'' regardless of the replica's metal content.[16]

The Commission believes the Act's and rule's definitions of ''imitation numismatic item'' cover an imitation coin that contains a different metal content from the original item where the imitation item ''*purports to be,* but in fact is *not,* an original.'' 15 U.S.C. 2106(4); 16 CFR 304.1(d) (emphasis added). Accordingly, such imitation coins should be marked ''copy'' and this notice should alert those who are not so marking their coins in the mistaken belief that the Act and rule do not apply of their compliance obligation. Moreover, even though the Act and rule address only the marking, and not the marketing, of imitation numismatic or political items, misrepresenting a copy as an original in advertising or marketing constitutes a ''deceptive act or practice'' under section 5 of the FTC Act, 15 U.S.C. 45.[17]

b. Require the Word ''Copy'' To Be Incused on Both Sides of Replicas of U.S. Coins

The rule currently requires that the word ''copy'' be marked on either side of the coin, 16 CFR 304.6(b)(2). Coin World suggested that the word ''copy'' be incused on both sides of the coin because unscrupulous sellers may take advantage of the fact that manufacturers may have inconspicuously woven the word ''copy'' into the original design elements of one side of the coin. This may be a particular problem for coins minted prior to 1836.[18] The Commission has concluded that a requirement that ''copy'' be marked on both sides of an imitation coin is not warranted. With exhibited coins, the potential buyer would normally have the chance to fully view and handle the coin, so the ''copy'' marking would be seen prior to purchase. Furthermore, as discussed above, if the seller misrepresents a copy as an original in advertising or marketing, such practice would be deceptive in violation of section 5 of the FTC Act, 15 U.S.C. 45.

B. Comments Relating to Expanding Coverage of the Act and Rule to Reproductions of All Antiques and Collectibles

The vast majority of the 350 comments submitted in response to the Commission's FRN advocated that the Act or rule be expanded to cover antiques and collectibles. In summary, these comments state that reproductions of many types of antiques and collectibles are being passed off as originals, causing harm to collectors and dealers. Many comments also assert that because of improvements in technology, even knowledgeable persons have difficulty distinguishing reproductions from the originals.

Collectors of a wide variety of items proposed expanding the rule. Such commenters included collectors of the following items: Victorian paper weights,[19] casino chips and gambling tokens,[20] custard glass,[21] American Pattern Glass,[22] thimbles,[23] antique fishing lures,[24] glass and porcelain electrical insulation devices related to the communications and power industries,[25] milk bottles and other dairy memorabilia,[26] antique fruit jars,[27] toy trains and related material,[28] and 19th Century homemade dolls.

1. The Source and Scope of the Passing Off Problem

The comments suggested that many categories of collectibles are subject to being passed off, and provided explanations for the problem. One commenter stated that since the passage of the Act in 1973 there has been a dramatic increase of reproductions in all areas of the antiques and collectibles market. Dealers and collectors alike have been fooled by reproductions they have purchased, believing them to be genuine antiques. The commenter stated that this deception translates into financial losses and builds a sense of mistrust in the antiques market.[29] Numerous commenters stated that because of improvements in manufacturing technology, the quality of reproductions has vastly improved to the point where reproductions are virtually indistinguishable from the originals.[30] One commenter pointed out

[12] *E.g.,* NAC; American Political Items Collectors (APIC). Larry Klug, APIC executive director, write, ''I can say, without pause, that the Hobby Protection Act has made a major difference in this collecting area over the past nearly 30 years—not only by identifying those items which are reproduced by having the date and word 'copy' on them, but also in stifling the actual reproduction of items in the first place.''

[13] According to Coin World, the U.S. Mint has reported that more than 139 million U.S. adults are collecting coins today, as compared with approximately 2 million just prior to 1999.

[14] Larry Krug, Americana Resources, Inc.

[15] Coin World.

[16] *Id.*

[17] *See FTC* v. *Hang-Ups Art Enters.,* 1997–1 Trade Cas. (CCH) ¶ 71,709 (C.D. Cal. January 30, 1996) (FTC alleged that defendants violated FTC Act section 5 by falsely representing that the art prints were the work of the named artists or that they were authorized by the artist; order prohibits defendants, in connection with marketing any artworks, from falsely representing that any artwork displaying an original signature or edition size designation is the work of a particular artist); FTC v. Magui Publishers, Inc., 1991–1 Trade Cas. (CCH) ¶ 69,425 (C.D. Cal. March 28, 1991) (FTC alleged that defendants violated FTC Act section 5 by misrepresenting that Salvador Dali had a role in the creation and production of the artwork, when, in fact, Dali was physically incapable of participating in the production of print editions of his work).

[18] Coin World. According to Coin World, they have seen the most abuses in copies of large cents coins minted prior to 1836.

[19] William C. Price.

[20] *E.g.,* Alex Cilento. Several commenters stated that they believed that the Act and rule should be amended to specifically include casino chips and tokens in the definition of imitation numismatic items. The commenters stated that such a modification would deter those who might consider counterfeiting casino chips and tokens.

[21] *E.g.,* Sarah I. Coulon.

[22] *E.g.,* Patricia Riemann.

[23] Kathy John.

[24] Franklin T. Lanham.

[25] *E.g.,* Tom Katonak, National Insulator Association.

[26] *E.g.,* James D. Weidenhammer.

[27] Tom and Denna Caniff.

[28] Ronald S. Morris, Train Collectors Association.

[29] Joy Harrington.

[30] *E.g.,* Bob and Janice Baltzell d/b/a Classic Treasure; Douglas N. Smith; and Sarah Campbell Drury, Candidate Member, American Society of

that some items are even being made from the original molds.[31]

Another commenter stated that since the 1998 review of the Act, there has been a tremendous increase in the number of reproductions, imported mainly from the Far East, with forged, fake, or misleading backstamps or other markings and only a paper label indicating the country of origin. The commenter pointed out that the paper labels are routinely removed and the items are then sold in flea markets, antique malls and on the Internet, and are represented as antiques.[32] Similarly, another commenter stated that American import companies contract with foreign factories, most often in China, to make reproductions of vintage American art pottery and art glass with replicas of the original American company marks. The commenter stated that the only indication that the product is a reproduction and/or of foreign origin is a tiny paper sticker that states, ''Made in China.'' The commenter pointed out that the stickers virtually never make it to the retail market.[33]

Several commenters stated that Internet trading makes it impossible to examine an item before purchasing it.[34] One dealer, who has been selling on the Internet for nearly eight years, stated that he is finding an increasing number of customers who are fearful of purchasing reproductions, particularly those who previously have had bad experiences with their Internet purchases.[35] Several commenters stated that Internet sales spread the ''fakes'' quickly, before dealers and the public can be warned in trade publications.[36] Another commenter reported that the Internet has increased the number of collectors; thus, there has been an increase in buyers who are less informed about reproductions.[37]

Although the comments do not present information sufficient to quantify or determine the amount of economic and other harm caused, they suggest several possible adverse effects of the passing off problem. For example, the comments suggest that individual buyers may pay considerably more than a product is worth, that owners of original antiques or collectibles that are heavily reproduced may lose the value of their investment, and that the uncertainty regarding the genuineness of antiques and collectibles may dissuade persons from purchasing originals or from becoming collectors, which also adversely affects businesses that deal in originals.

2. Proposals To Expand Coverage of the Rule to Non-Covered Products

Most commenters recommended that the Commission require that antique reproductions be clearly and permanently marked ''copy.'' [38] One commenter stated that permanently marking items as ''copy'' would eliminate the problem of confusion between the actual antique and the reproduction. That commenter stated that adding ''copy'' to the product would require only a small adjustment during the manufacturing process.[39] Another commenter argued that the only reason not to permanently mark items as reproductions is if the intent is to co-mingle them with the antiques in order to ''fool the public.'' [40]

The commenters varied in their approaches to the types of additional information that they proposed be disclosed on the items, including requiring manufacturers to mark new items with: the date of manufacture; [41] the manufacturer's name; [42] and/or the place of manufacture.[43] One commenter's solution to temporary paper country-of-origin labels was to embed the country-of-origin and the date permanently into the underside of the product.[44] One dealer suggested that manufacturers who reissue old patterns in exact form and color should be required to use a permanent mark that would identify the date of manufacture.[45]

For several reasons, the Commission does not propose to adopt the changes requested by the commenters. First, the Act does not provide the Commission with the legal authority to expand the rule's coverage to all antiques and collectibles. The plain language of the Act encompasses only numismatic and political items and directs the Commission to promulgate rules regarding the marking of these covered products only. 15 U.S.C. 2101. For this reason, the Commission cannot amend the rule to include products not specified in the Act.

Second, the Commission believes that existing Federal and State laws provide remedies for some issues the comments raise. For example, the majority of comments cited imported reproductions as the most significant source of passed off goods. Current U.S. laws and regulations already require country-of-origin markings for goods imported into the United States. Specifically, country-of-origin marking for imports falls under the jurisdiction of the U.S. Bureau of Customs and Border Protection (''CBP''), U.S. Department of Homeland Security, which enforces the Tariff Act of 1930. 19 U.S.C. 1304. U.S. customs laws require each imported article produced abroad to be marked legibly, indelibly, and permanently in a conspicuous place to indicate the country of origin. The Tariff Act also allows the container of an imported good to bear the origin marking rather than the good itself, as long as the good reaches the ultimate purchaser in the container. Under the Tariff Act, a permanent marking is a marking that will remain on the article or container until it reaches the ultimate purchaser, although the marking may be removed by the ultimate purchaser and need not be of a permanence to remain affixed once in his or her possession.[46] This marking may not be removed prior to delivery to the ultimate purchaser, however, and anyone who removes this marking prior to such delivery could be subject to prosecution and criminal penalties.

The Commission staff has brought the foreign origin marking concerns raised in this proceeding to the CBP's attention because its regulations govern several of the problems discussed in the comments. For example, numerous commenters stated that certain country-of-origin labels are being deliberately removed before reaching the ''ultimate purchaser.'' The CBP urges persons with information regarding the violative removal of required country-of-origin markings to write to: Commercial Enforcement Branch, Office of Field Operations, U.S. Bureau of Customs and Border Protection, 1300 Pennsylvania Ave., NW., Washington, DC 20229, or to call CBP's toll free Commercial Fraud Hotline, 1–800-BE-ALERT. The CBP staff suggest consumers provide them with as much of the following

Appraisers. These commenters asserted that while they consider themselves ''experts'' in certain categories of antiques and collectibles, it is impossible to keep up with the latest reproductions. They stated that some reproductions are well made and appear to be almost exact duplicates of original items.

[31] Bob and Janice Baltzell d/b/a Classic Treasure.

[32] Mary Bitting Page, Granny's Attic.

[33] Marcus Page.

[34] *E.g.,* Michael B. Young.

[35] Larry Krug, Americana Resources, Inc.

[36] Antique Dealers Association of Berks County, Inc.

[37] NAC.

[38] *E.g.,* Samuel Clark.

[39] *Id.*

[40] Luan B. Watkins.

[41] *E.g.,* Mary Biting Page; Wagner and Griswold Society; Penny Reed.

[42] *E.g.,* LeAnne Milliser; Virginia H. Cori.

[43] *E.g.,* Vivian Riegelman.

[44] Richard Dudley. The commenter stated that this can be done by simply modifying the mold with an inset.

[45] LeAnne Milliser, Golden Age Treasures.

[46] *But see* 19 CFR 1343(c)(2), which requires that imported Native American-style jewelry be indelibly marked with the country of origin by cutting, die-sinking, engraving, stamping, or some other permanent method.

information as possible: The port to which the questionable merchandise was shipped; the importers' names and/or the repurchasers' names; the kind of merchandise at issue; and any information regarding the alleged deliberate removal of the paper country-of-origin label.

Further, intentionally passing off reproductions as antiques can be prosecuted as criminal fraud or as civil fraud in a lawsuit by a buyer.[47] Additionally, the Lanham Act provides injured persons with a private right of action against certain false or misleading representations regarding goods or false designation of origin, *e.g.*, reproductions being passed off as original items. 15 U.S.C. 1125. Further, a pattern or practice of significant affirmative misrepresentations or failure to disclose material information relating to reproductions passed off as originals may violate the FTC Act.[48]

In addition to the deliberate removal of country-of-origin labels, many commenters suggested that the lack of truly permanent country-of-origin labels on reproductions can result in these reproductions inadvertently being passed off as originals in the secondary market. This could be addressed, at least in part, through greater enforcement of labeling requirements to the initial seller and through educational remedies.

The record indicates that there are many non-legal resources available to educate consumers about antiques and collectibles and thus reduce consumers' susceptibility to the practice of passing off. For example, several newsletters and hobby newspapers regularly warn and advise buyers of antiques and collectibles about reproductions of specific items and classes of items.[49] The comments also indicate that there are collector clubs for many categories of collectibles that provide members with similar information.[50] The Commission staff will continue to explore whether there is a role for the Commission in these efforts to increase consumer awareness.

IV. Conclusion

The comments uniformly favor retention of the rule and state that there is a continuing need for the rule with regard to currently covered products, *i.e.*, imitation numismatic and political items; that the rule benefits consumers and the industry; that the rule does not impose substantial economic burdens; and that the benefits of the rule outweigh the minimal costs it imposes.

Although many comments recommended that the rule be expanded to cover all antiques and collectibles, the Commission does not have the authority under the Act to expand the rule in this manner. Furthermore, there are a variety of legal and non-legal resources that address many of the issues raised by the commenters favoring expansion of the rule's coverage. Accordingly, the Commission has determined to retain the current Rule and is terminating this review.

List of Subjects in 16 CFR Part 304

Hobbies, Labeling, Trade practices.

Authority: The Federal Trade Commission Act, 15 U.S.C. 41–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

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BILLING CODE 6750–01–P

[47] Section 2–721 of the Uniform Commercial Code provides civil remedies for material misrepresentation and fraud in sales transactions.

[48] Section 5 of the FTC Act prohibits deceptive acts or practices in commerce. 15 U.S.C. 45. A deceptive act or practice is one that is likely to mislead consumers acting reasonably under the circumstances. As a matter of policy, however, the Commission does not generally intervene in individual disputes. For the most part, the instances of passing off described in the comments reflect specific individual transactions, rather than a patter or practice of passing off. Where the Commission obtains evidence of such a pattern or practice, however, it may take action.

[49] *E.g.,* Antiques & Collectors Reproduction News, published by Mr. Mark Chervenka of Desmoines, Iowa.

[50] *E.g.,* NAC. This commenter noted that many collecting clubs have educational programs, such as newsletters, Web sites, seminars or workshops at club conventions, about reproductions.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Penicillin G Potassium in Drinking Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Vétoquinol N.–A., Inc. The ANADA provides for the use of penicillin G in the drinking water of turkeys for the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*.

DATES: This rule is effective March 3, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Vétoquinol N.–A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada J0K 1H0, filed ANADA 200–307 that provides for use of Penicillin G Potassium, USP, in the drinking water of turkeys for the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae*. Vétoquinol N.–A., Inc.'s Penicillin G Potassium, USP, is approved as a generic copy of Fort Dodge Animal Health's Penicillin G Potassium, USP, approved under NADA 55–060. The ANADA is approved as of January 29, 2004, and the regulations are amended in 21 CFR 520.1696b to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1696b is amended by revising paragraph (b) to read as follows: