1 to subpart P of part 404 of our regulations, we incorporate them by reference in the SSI program in § 416.925 of our regulations, and apply them to claims under both title II and title XVI of the Act.

How do we use the listings?

The listings are in two parts. There are listings for adults (part A) and for children (part B). If you are an individual age 18 or over, we apply the listings in part A when we assess your claim, and we do not use the listings in part B.

If you are an individual under age 18, we first use the criteria in part B of the listings. If the criteria in part B do not apply, we may use the criteria in part A when those criteria give appropriate consideration to the effects of the impairment(s) in children. (See §§ 404.1525 and 416.925.)

If your impairment(s) does not meet any listing, we will also consider whether it medically equals any listing, that is, whether it is as medically severe as an impairment in the listings. (See §§ 404.1526 and 416.926.)

What if you do not have an impairment(s) that meets or medically equals a listing?

We use the listings only to decide that you are disabled or that you are still disabled. We will not deny your claim or decide that you no longer qualify for benefits because your impairment(s) does not meet or medically equal a listing. If you have a severe impairment(s) that does not meet or medically equal any listing, we may still find you disabled based on other rules in the ''sequential evaluation process.'' Likewise, we will not decide that your disability has ended only because your impairment(s) no longer meets or medically equals a listing.

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: January 15, 2008.

Michael J. Astrue,

Commissioner of Social Security.

[FR Doc. E8–5022 Filed 3–17–08; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. 2008N–0011]

RIN 0910–AG03

Defining Small Number of Animals for Minor Use Designation

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The designation provision of the Minor Use and Minor Species Animal Health Act of 2004 (MUMS act) provides incentives to animal drug sponsors to encourage drug development and approval for minor species and for minor uses in major animal species. Congress provided a statutory definition of ''minor use'' that relied on the phrase ''small number of animals'' to characterize such use. At this time, FDA is proposing to amend the implementing regulations of the MUMS act. In response to Congress' charge to the agency to further define minor use, this amendment proposes a specific ''small number of animals'' for each of the seven major animal species to be used in determining whether any particular intended use in a major species is a minor use.

DATES: Submit written or electronic comments on the proposed rule by July 16, 2008. Submit comments regarding information collection by April 17, 2008 to OMB (see **ADDRESSES**).

ADDRESSES: You may submit comments, identified by Docket No. 2008N–0011 and RIN number 0910–AG03, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Information Collection Provisions: Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB).To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Margaret Oeller, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9005, e-mail: *Margaret.Oeller@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Definition of Minor Use

The MUMS act (Public Law 108–282) amended the Federal Food, Drug, and Cosmetic Act (the act) to provide incentives for the development of new animal drugs for use in minor animal species and for minor uses in major animal species. The MUMS act defines ''minor use'' as ''the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually'' (section 201(pp) of the act (21 U.S.C. 321(pp)). The major species are cattle, horses, swine, chickens, turkeys, dogs, and cats (21 U.S.C. 321(nn)).

Prior to enactment of the MUMS act, FDA defined minor use by regulation to

mean, ''the use of: * * * (b) new animal drugs in any animal species for the control of a disease that (*1*) occurs infrequently or (*2*) occurs in limited geographical areas'' (48 FR 1922; January 14, 1983 (former § 514.1(d)(1) (21 CFR 514.1(d)(1))). The MUMS act narrowed this definition by restricting it to uses ''in only a small number of animals annually'' (21 U.S.C. 321(pp)).

The legislative history of the MUMS act indicates that Congress intended that FDA further define minor use in a major species by regulation and that it do so ''by evaluating, in the context of the drug development process, whether the incidence of a disease or condition occurs so infrequently that the sponsor of a drug intended for such use has no reasonable expectation of its sales generating sufficient revenues to offset the cost of development'' (S. Rpt. 108–226 at 12–13). The legislative history also notes that the new statutory definition for minor use ''incorporates the existing definition in the Code of Federal Regulations (21 CFR 514.1(d)(1)) with a further limitation to small numbers to assure that such intended uses will not be extended to a wider use'' (S. Rept. 108–226 at 12–13).

Therefore, while the MUMS act establishes incentives for animal drug development for minor uses, it also limits the availability of those incentives in order to prevent them from stimulating ''wider use'' of new animal drugs marketed under the MUMS act provisions.

Consistent with these dual aims of stimulating animal drug development for minor uses in major species and at the same time preventing ''wider use'' of such new animal drugs, the agency is proposing to define the term ''small number of animals'' for each major species that would constitute the upper limit of a ''minor use'' under the MUMS act. In keeping with the goal of creating a drug development incentive, the proposed definition would establish the number of animals eligible to be treated annually based on the number of animals that represents a drug market value that (relative to drug development costs) would not be likely to be pursued in the absence of the MUMS act incentives. Furthermore, as explained in the following section I.B of this document, FDA believes it is necessary to establish ''small number of animals'' differently for companion animals than for food-producing animals.

B. Companion Animals vs. Food-Producing Animals

The issue of considering companion animals and food-producing animals separately in the context of establishing small numbers of animals was raised in comments on the MUMS designation proposed rule (70 FR 56394; September 27, 2005).

One of the comments stated that the agency and sponsors would be best served by separating requirements for companion and food-producing animals because ''this separation would provide information clearly focused on the information necessary for each group'' (Ref. 1).

A second comment requested that the agency ''consider separation of the requirements for companion animals from that for food-producing animals, as it is difficult to generalize across the two categories'' (Ref. 2).

A third comment urged FDA to establish different sets of criteria for major species of food-producing animals and companion animals because ''economic criteria play differently into decisions to administer drugs to these two types of animals'' (Ref. 3).

The agency generally agrees that food-producing and companion animals should be considered separately with respect to establishing small numbers, and notes that one of the principal reasons for considering food-producing and companion animals differently is that the decision to treat food-producing animals is almost exclusively based on an assessment of the economic value of the animals at the time treatment is needed. In addition, very often this decision involves administering a drug to all animals in a herd or flock, not just those showing signs of disease. Because the decision to administer a drug may be made more conservatively than for companion animals but, once made, often involves the exposure of more animals, there is no clear basis for estimating the likelihood of drug administration to individual food-producing animals.

Other factors to consider are that there are much larger absolute numbers of food-producing animals than companion animals (in the case of chickens, approximately 9 billion) (Ref. 4), and that food-producing animals tend to be geographically concentrated to a greater extent than companion animals (Ref. 5). Each of these factors supports establishing ''small numbers of animals'' for companion animals differently than ''small numbers of animals'' for food-producing animals.

When FDA proposed regulations to implement the designation provision of the MUMS act, the preamble contained considerable discussion regarding the definition of ''minor use,'' including the issues surrounding the use of the phrase ''small number of animals'' in the statutory definition of minor use. (See section II.A.2 Minor Use of 70 FR 56394 at 56395.) Ultimately, the agency indicated that it did not have enough information to propose a ''small number of animals'' for each major species at that time, but indicated its intention to do so in the future, and requested information to facilitate that process.

In response to this request, FDA received four comments concerning ''small numbers of animals'' and minor use which the agency responded to in the preamble of the MUMS designation final rule. (See section III.B of 72 FR 41010 at 41013.) These comments were general in nature. This may be attributed, in part, to animal drug sponsors considering specific information regarding the cost of drug development, and the process by which they make decisions to pursue drug development, to be, ''for the most part, confidential'' (Ref. 2). However, the agency was able to obtain information regarding average animal drug development costs as well as typical drug treatment costs for the seven major species. This information was obtained by contracting with a source with significant knowledge of the animal pharmaceutical industry that was also capable of collecting information from a large number of other sources (Ref. 6). From this source, the agency was also able to obtain general information regarding the incidence or prevalence of a large number of diseases and conditions of dogs, cats, and horses. Similar information regarding disease incidence or prevalence was not readily available for major food-producing species.

In fact, in spite of repeated agency requests to the animal health industry to identify potential conditions of food-producing animals that might qualify as minor uses, very few conditions have been suggested; for example babesiosis in cattle.

Therefore, following a careful analysis of the information noted previously, and based on early experience making designation determinations on a case-by-case basis, the agency is now proposing the establishment of a ''small number of animals'' for each of the seven major animal species.

II. Proposed Regulation

A. ''Small Numbers'' for Major Species of Companion Animals

1. The Value of Exclusivity

There are three drug development incentives established by the Orphan Drug Act (Public Law 97–414) that are associated with human orphan product development: Seven years of exclusive marketing, an approximately 50 percent

reduction in development costs via tax reductions, and eligibility for grants to support development costs. Designated MUMS drugs are currently eligible for 7 years of exclusive marketing (section 573(c) of the act) (21 U.S.C. 360ccc–2(c)), and eventually will be eligible for grants (section 102(b)(8) of the MUMS act). A tax incentive for animal drug development was not included in this legislation. The designation provisions of the MUMS act went into effect upon enactment. Therefore, FDA must define ''small numbers'' as soon as possible.

Consistent with the intent and the language of the MUMS act, ''small number'' for each major companion animal species (horses, dogs, and cats) should represent a drug market value that (relative to drug development costs) would not be likely to be pursued in the absence of the MUMS act incentives. While incentives in addition to marketing exclusivity, such as the MUMS grant provisions, should they become available, would be expected to increase the likelihood of developing drugs for markets smaller than the proposed small number thresholds, the increase in incentives would not alter the small numbers themselves.

To estimate the value of 7 years of exclusive marketing rights, we have examined the marketing exclusivity established by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) (Public Law 100–670) as a benchmark for MUMS exclusivity. GADPTRA provides 5 years of exclusivity for the first-time approval of a drug in animals (section 512(c)(2)(F) of the act) (21 U.S.C. 360b(c)(2)(F)). In enacting GADPTRA, Congress indicated that it viewed this term of exclusivity as a sufficient return on investment prior to generic competition to provide an incentive for the pioneer sponsor to develop a drug. Together with information regarding average animal drug development costs obtained by the agency (Ref. 6), we can calculate the relative value of the 5-year GADPTRA incentive. A basic principle of animal drug product development embedded in these data is that a sponsor will generally need to perceive a market potential in the third year of marketing equal to the development cost of the product in order to pursue development (Ref. 6). This third year market is apparently considered the mature market for the drug or, in industry parlance, the ''going'' market (Ref. 6) and can serve as a basis for calculating the entire market potential of a drug prior to generic competition.

As a hypothetical example, for a drug with a $15,000,000 ($15M) development cost for a particular intended use, the third year market would need to be perceived to be $15M in order to support product development. In this example, we project a ramp up to this ''going'' market value of $5M in the first year of marketing and $10M in the second. This means that under the 5-year term of exclusivity provided by GADPTRA, for a first-time approval of a drug in animals, a market prior to generic competition sufficient to justify pioneer sponsor investment relative to a $15M investment is $60M (i.e., $5M in year 1 + 10M in year 2 + 15M in year 3 + 15M in year 4 + $15M in year 5).

There may be a number of ways of interpreting the value of the additional 2 years of exclusivity provided to MUMS drugs; but, the most useful interpretation of the value of this extended marketing exclusivity is that it provides a sponsor an opportunity to lower its perception of an acceptable ''going'' market value to support drug development because the sponsor has longer to recoup development costs without competition. In the previous example, this would mean that the $60M fair and reasonable market value prior to competition established under GADPTRA could be spread over 7 years instead of 5 with the result that the ''going'' market value (third year market value) for a drug with development costs of $15M would only need to be $10M in order to support drug development (i.e., $3.5M + 6.5M + 10M + 10M + 10M + 10M + 10M). Therefore, assuming for the purposes of a general estimate that the ramp-up to a going market is roughly linear as shown in the example, in a practical sense, the economic value of the 7 years of exclusive marketing rights for MUMS drugs is to lower the ''going'' market value needed to support drug development by about one-third. It should be noted that MUMS exclusive marketing rights provide protection from competition from all products with the same drug, same dosage form, and same intended use rather than just from generics under GADPTRA and this provides additional value to this incentive.

Having estimated the market value of this MUMS incentive as a one third reduction in the ''going'' market value, in order to define ''small number,'' the agency's task is then to estimate the number of animals of each major companion animal species the drug treatment of which represents a drug market value, that is about two-thirds of the estimated cost of drug development for each of these species.

The agency is well aware of the enormous variability that will be encompassed by one estimate of drug development cost for each major companion animal species. For companion animals, an estimated range of drug development costs for first-time approval of an animal drug is $10 to $20 million, with additional estimates as low as $5 million (Ref. 6). Based on these estimates, the agency believes $15 million represents the average drug development cost.

2. Additional Factors Unique to Companion Animals

The number of major species companion animals eligible for treatment on an annual basis that represents a drug market value roughly equivalent to two-thirds of the estimated drug development cost for these major species depends on a large number of factors affecting the drug treatment value of individual animals. For purposes of this discussion, drug treatment value means the portion of the cost of treating an animal with a given drug that is returned to the sponsor of the drug. Again, the agency acknowledges the great variability that will be encompassed in one estimate of drug treatment value for individual animals of each major companion animal species. The drug treatment value of individual animals is a portion of the cost that animal owners are willing to pay to have animals treated for a given condition. The sum of the drug treatment values of all of the animals treated with a given drug over the course of a year represents the sponsor's annual market value of that drug.

Two of the most basic factors affecting drug market value are the species involved, which significantly affects the amount that people are willing to pay to treat an individual animal, and the percentage of the eligible population of animals that is actually treated under typical circumstances.

Drug treatment values must be considered in the context of the cost of ancillary veterinary services associated with diagnosis and subsequent treatment. Clearly, costs ancillary to drug costs may decrease the likelihood of a decision to treat a given animal. For a given drug, the drug treatment value, the ancillary cost of treatment, the practitioner's decision to markup the drug cost to the client, and the decision of the client to accept the total cost of treating an animal are all inter-related. As the drug treatment value increases, other costs may decrease in order for the total cost of treatment to be made acceptable to a given client. Available information regarding the amount that people are willing to pay to treat representative conditions in the three

major companion animal species is quite variable (Ref. 6). However, based on available information, the agency concludes that companion animal owners generally will pay more to treat a horse than a dog, and more to treat a dog than a cat (Ref. 6). Based on available information, the agency further concludes that a reasonable annual drug treatment value for conditions significantly affecting the health of individual animals of these species is about $500 for horses, about $350 for dogs, and about $200 for cats (Ref. 6).

For any given condition, many animals that are eligible to be treated will not actually be treated and the decision to treat will depend to a large extent on the nature of the condition and the cost of treatment. While an estimate of the likelihood of treatment must be very general to represent the large variability encompassed by that estimate, based on the factors described previously and currently available information (Ref. 7), the agency believes that it is reasonable to estimate a 50 percent non-treatment rate across all major companion animal species.

Defining small numbers for companion animal species must take into account the uncertainty inherent in the estimates of prevalence or incidence of diseases or conditions that occur in relatively small numbers of animals. Therefore, a disease prevalence or incidence estimate submitted with a request for minor use designation will be considered relative to its degree of uncertainty to enable the agency to be 90 percent confident that the actual prevalence or incidence of the disease at issue is at or below the estimate, and that the resulting estimate is below the small number threshold.

Even reasonably good estimates, such as those based on published articles involving actual tabulation of a number of cases of the disease or condition at issue gathered at multiple sites or over an extended time, or results of surveys involving about a hundred respondents, appear to present uncertainties on the order of +/- 10 percent around the estimate. Since at least +/- 10 percent uncertainty is likely to exist for most estimates, based on an assumption of normal distribution, the agency has also increased the proposed small numbers for companion animals by approximately 13 percent to account for this. The practical effect of this approach is that an estimated prevalence or incidence that is on the order of 12 percent below the proposed threshold could be accepted as a small number with 90 percent confidence that it is truly below the threshold when the uncertainty associated with the estimate is on the order of +/- 10 percent or less, but could be rejected as a small number if the uncertainty associated with the estimate is sufficiently above 10 percent.

Finally, proposed thresholds were somewhat increased to achieve ''round'' numbers. Given the variability associated with several of its assumptions, the agency believes that this is acceptable.

In summary, the following assumptions underlie the proposed ''small numbers'' definition for companion animals:

(1) A reasonably representative development cost for a new companion animal drug is about $15 million.

(2) Without incentives, a sponsor will generally need to perceive a market potential in the third year of marketing equal to the development cost of the product in order to pursue development.

(3) Due to the extended exclusive marketing rights, the ''going market'' for a MUMS product can be about one-third less than the market normally required for a sponsor to pursue drug development.

(4) Although the amount individual animal owners spend on companion animals is highly variable, companion animal owners generally will pay more for the treatment of a horse than for a dog and more for a dog than a cat.

(5) Treatment costs ancillary to drug treatment value decrease the likelihood of a decision to treat a given animal and provide no return on investment to sponsors.

(6) The drug treatment value for a horse is about $500, for a dog about $350, and for a cat about $200.

(7) There is about a 50 percent non-treatment rate across all major companion animal species.

(8) There is about 10 percent uncertainty in even the best published estimates of disease incidence or prevalence in companion animals.

A ''small number of animals'' for each of the three major companion animal species can be calculated by incorporating these assumptions into the following formula:
[average companion animal drug development cost in dollars] - 1/3 = [minor use ''going market'' in dollars] ÷ [average drug treatment value in dollars for each species] = [a preliminary small number of animals] x 2 (untreated factor) + 13% (uncertainty factor) + (increase to ''round'' number) = [species specific ''small number of animals'']

The agency recognizes that there is considerable variability within each of these assumptions. However, in order to consistently and fairly implement the designation provision of the MUMS act, FDA believes it is vital to establish one ''small number'' for each major species. The agency's task is to set these numbers so that they can be applied to a wide variety of requests for minor use designation. This is the same task that Congress undertook when it established by statute a threshold number of 200,000 for human orphan drugs (section 526(a)(2) of the act) (21 U.S.C. 360bb(a)(2)).

Following this approach, the agency proposes defining ''small numbers'' for the major companion animal species as: 50,000 horses, 70,000 dogs, and 120,000 cats affected annually.

B. ''Small Numbers'' for Major Species of Food-Producing Animals

For the reasons discussed in Background section I.B. of this document, FDA is proposing to establish ''small numbers'' in a different manner for food-producing animals than for companion animals.

Just as it did with respect to establishing ''small numbers'' for companion animals, the agency looked for a benchmark to serve as a basis for quantifying a threshold small number for each food-producing major species. Consistent with comments received on the MUMS designation proposed rule (Refs. 1 and 3), the benchmark that the agency found to be most appropriate for food-producing animals is based on a comparison between major and minor food-producing species, and the minor food-producing species most directly comparable to major food-producing species with respect to drug development costs, animal husbandry, and the nature and scope of drug use is sheep.

The market for new animal drug sales represented by that portion of the U.S. sheep population that could reasonably be treated on an annual basis qualifies for the incentives of MUMS designation because sheep are a minor species. The market for sheep drugs thus represents a market for food-producing animal species that Congress determined merited MUMS act incentives in order to stimulate drug development. Therefore, it is reasonable that an intended use in a major food-producing species that represents a similar size market should also qualify for these incentives.

To serve as a reasonable estimate of the size of the drug market for sheep, and to permit an equitable comparison across all major food-producing species, the agency used the biomass of sheep presented to slaughter facilities in the United States in 2004 (the year of

passage of the MUMS act) as the basis for extrapolation to establish small numbers for major food-producing species. Because new animal drugs are usually dosed by weight, biomass serves as a reasonable basis for extrapolation because the amount of drug sold to treat a particular food-producing species over the course of a year roughly correlates to the total weight, or biomass, of the animal species being treated during that year.

The biomass of sheep going to slaughter in 2004 represents slightly less than 50 percent of the total biomass of sheep existing in that year and, therefore, represents an assumption that 50 percent of sheep existing in 2004 might have been treated with a given drug during that year. Given the limited amount of information available regarding disease prevalence or incidence in food-producing animals, treatment of 50 percent of the sheep population by a given drug is considered by the agency to be a reasonable estimate of the maximum drug market for the species. As previously noted, this estimate also represents a food-producing species drug market that Congress established as eligible for MUMS act incentives.

The amount of biomass from sheep (including lambs) arriving at slaughter facilities in 2004 (the total live weight of animals presented for slaughter) is reported by the U.S. Department of Agriculture (USDA) (Ref. 8) to be 380,000,000 (380M) pounds (lbs). Therefore, we propose to define the ''small number'' that represents ''minor use'' for each major food-producing animal species as the number of animals going to slaughter in 2004 that produced a cumulative biomass equivalent to 380M lbs/year.

Following this approach, based on USDA statistics for 2004 for cattle, pigs, turkeys and chickens (Refs. 4 and 8), 380M pounds of biomass (live weight at slaughter) roughly equates to 310,000 cattle (at 1,240 lbs/animal); 1,450,000 pigs (at 266 lbs/animal); 14,000,000 turkeys (at 27 lbs/bird); and 72,000,000 chickens (at 5.3 lbs/bird).

C. Small Numbers as a Limitation to ''Wider Use''

As noted previously, the legislative history of the MUMS act states that the statutory definition for minor use ''incorporates the existing definition in the Code of Federal Regulations (21 CFR 514.1(d)(1)) with a further limitation to small numbers to assure that such intended uses will not be extended to a wider use'' (S. Rept. 108–226 at 12 13). The agency believes that the ''small number of animals'' of each major species being proposed to clarify the definition of ''minor use'' meets the dual goals that Congress established in the legislative history of the MUMS act to provide added incentives for animal drug development while assuring that the proposed ''small numbers'' will not result in minor uses being ''extended to a wider use'' in major animal species.

D. Proposed ''Small Numbers''

Based on an assessment of all of the factors noted previously, and for the purpose of further defining ''minor use'' under the Minor Use and Minor Species Animal Health Act of 2004 and 21 CFR 516.3, the agency proposes to define ''small numbers'' for each major species as equal to or less than each of the following numbers:

TABLE 1.—PROPOSED SMALL NUMBERS FOR EACH MAJOR SPECIES

Species	Small Number
Horses	50,000
Dogs	70,000
Cats	120,000
Cattle	310,000
Pigs	1,450,000
Turkeys	14,000,000
Chickens	72,000,000

Finally, as noted in the response to comments on the proposed MUMS designation rule (see 72 FR 41010 at 41012), paragraph (c) of § 516.21 (21 CFR 516.21) (Documentation of minor use status) is unnecessary once small numbers of animals have been established. Because the agency is proposing to establish small numbers of animals at this time, the agency is also proposing to remove § 516.21(c) and its associated burden on the animal pharmaceutical industry.

III. Legal Authority

FDA's authority for issuing this proposed rule is provided by the Minor Use and Minor Species Animal Health Act of 2004 (section 571 of the act) (21 U.S.C. 360ccc *et seq.*). When Congress passed the MUMS act, it directed FDA to publish implementing regulations (see 21 U.S.C. 360ccc note). In the context of the MUMS act, the statutory requirements of section 573 of the act, along with section 701(a) of the act (21 U.S.C. 371(a)) provide authority for this proposed rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act.

IV. Analysis of Economic Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule is only expected to slightly reduce the administrative effort of ''minor use'' requestors while imposing no additional costs, the agency does not believe that this proposed rule would have a significant economic impact on a substantial number of small entities. FDA requests comment on this issue.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceeded this amount.

FDA previously published both a proposed rule and final rule on the MUMS designation system. Each of these publications included analyses of the expected economic impacts of the creation and administration of the MUMS designation system as required by the Executive order and two statutes mentioned in the previous paragraphs. The final rule presented estimates of the annual costs of the MUMS designation system of about $65,000 annually. Additionally, the final rule provided some discussion of, but was not able to quantify, the expected benefits of the rule.

The final rule included a statement that it would address the issue of

establishing a definition of ''small number'' of animals in a future rulemaking. This proposed rule proposes that definition of ''small number'' of animals for each of the seven major animal species as defined by the MUMS act, based on the data and analysis as described previously in this preamble.

This proposed rule would set an upper limit on the number of animals of each of the seven major animal species for which a request for designation could be made under the ''minor use'' provisions of the MUMS designation final rule. FDA does not have any additional information to show that these proposed threshold numbers would significantly affect the expected number of MUMS designation requests that are received by the agency each year (estimated at 75 requests per year in the MUMS designation final rule). The proposed definition of a ''small number'' of each of the seven major species reduces the ambiguity for ''minor use'' requestors. Additionally, this proposed rule would provide for a small reduction in administrative effort by ''minor use'' requestors who would no longer be required to provide additional information on potential markets and drug development costs due to the proposed deletion of § 516.21(c). As such, FDA has determined that the proposed rule would not impose any additional costs or provide any further health benefits beyond those contained in the MUMS designation final rule.

V. Paperwork Reduction Act of 1995

This proposed rule does not contain new information collection provisions that would be subject to review by OMB, under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520).

Title: Setting ''Small Numbers of Animals'' for Determining Minor Use

Description: This proposed rule is intended to revise the minor use provisions of 21 CFR part 516, subpart B. Part 516 contains the implementing regulations for the Minor Use and Minor Species Animal Health Act of 2004, and subpart B contains the designation provisions for minor use and minor species new animal drugs. Currently, requests for minor use designation are considered case-by-case by the agency based on product-specific financial information supporting minor use status included in the request. In order to further define minor use, this rule proposes seven threshold ''small numbers of animals,'' one for each major species, based on industry-wide economic or animal production data. With these numbers in place, drug sponsors requesting minor use designation will no longer be required to submit confidential product-specific financial information, as currently required in § 516.21(c), thus lowering their reporting burden somewhat. However, we anticipate that most requests for designation will be for minor species, not minor use, and furthermore, the current requirement for financial information is only one part of a request for designation, therefore, the paperwork burden currently assigned to 21 CFR 516.20 will not be affected significantly.

Information collection requirements in this section were approved by OMB and assigned OMB control number 0910–0605.

VI. Environmental Impact

We have carefully determined under 21 CFR 25.30(h) 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.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has tentatively concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Public comment to Docket No. 2005N–0329, comment EC3, received February 2, 2006, submitted by American Veterinary Medical Association (AVMA), signed by Elizabeth Curry-Galvin.

2. Public comment to Docket No. 2005N–0329, comment C5, received January 26, 2006, submitted by Animal Health Institute, signed by Richard Carnevale.

3. Public comment to Docket No. 2005N–0329, comment EMC3, received December 12, 2005, submitted by Keep Antibiotics Working, signed by Rebecca Goldburg and Steve Roach.

4. USDA/National Agricultural Statistics Service, ''Poultry Slaughter 2004 Annual Summary,'' February 2005.

5. USDA/Animal and Plant Health Inspection Service, ''2004 United States Animal Health Report,'' August 2005.

6. Brakke Consulting, Inc., ''Disease Incidence Rates, Drug Development and Treatment Costs,'' September 2005.

7. AVMA, ''U.S. Pet Ownership & Demographics Sourcebook,'' 2002.

8. USDA/National Agricultural Statistics Service, ''2004 Livestock Slaughter Report,'' March 2005.

List of Subjects in 21 CFR Part 516

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 516 be amended as follows:

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

1. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

2. Amend § 516.3 by adding a new definition in alphabetical order to paragraph (b) as follows:

§ 516.3 Definitions.

* * * * *

(b) * * *

Small number of animals means equal to or less than 50,000 horses, 70,000 dogs, 120,000 cats, 310,000 cattle,

1,450,000 pigs, 14,000,000 turkeys, and 72,000,000 chickens.

* * * * *

§ 516.21 [Amended]

3. Amend § 516.21 by removing paragraph (c).

Dated: January 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy.

[FR Doc. E8–5385 Filed 3–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–149856–03]

RIN 1545–BD01

Dependent Child of Divorced or Separated Parents or Parents Who Live Apart; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of public hearing on proposed rulemaking.

SUMMARY: This document contains a notice of public hearing on proposed regulations relating to a claim that a child is a dependent by parents who are divorced, legally separated under a decree of separate maintenance, agreement, or who live apart at all times during the last 6 months of the calendar year.

DATES: The public hearing is being held on April 3, 2008, at 10 a.m. The IRS must receive outlines of the topics to be discussed at the hearing by March 26, 2008.

ADDRESSES: The public hearing is being held in Room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

Send submissions to: CC:PA:LPD:PR (REG–149856–03), Room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–149856–03), Couriers Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC or sent electronically, via the IRS internet site via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS–REG–149856–03).

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, Victoria Driscoll (202) 622–4920; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Regina Johnson (202) 622–7180 (not toll free numbers).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed regulations (REG–149856–03) that was published in the **Federal Register** on Wednesday, May 2, 2007 (72 FR 24192).

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing that submitted written comments by July 31, 2007, must submit an outline of the topics to be discussed and the amount of time to be devoted to each topic (signed original and eight (8) copies).

A period of 10 minutes is allotted to each person for presenting oral comments.

After the deadline for receiving outlines has passed, the IRS will prepare an agenda containing the schedule of speakers. Copies of the agenda will be made available, free of charge, at the hearing.

Because of access restrictions, the IRS will not admit visitors beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** section of this document.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Associate Chief Counsel, Legal Processing Division (Procedures and Administration).

[FR Doc. E8–5451 Filed 3–17–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–127391–07]

RIN 1545–BH02

Guidance Under Section 664 Regarding the Effect of Unrelated Business Taxable Income on Charitable Remainder Trusts; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to a notice of proposed rulemaking.

SUMMARY: This document contains corrections to a notice of proposed rulemaking (REG–127391–07) that was published in the **Federal Register** on Friday, March 7, 2008 (73 FR 12313) providing guidance under Internal Revenue Code section 664 on the tax effect of unrelated business taxable income (UBTI) on charitable remainder trusts.

FOR FURTHER INFORMATION CONTACT: Cynthia Morton at (202) 622–3060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The correction notice that is the subject of this document is under section 664 of the Internal Revenue Code.

Need for Correction

As published, a notice of proposed rulemaking (REG–127391–07) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of a notice of proposed rulemaking (REG–127391–07), which was the subject of FR Doc. E8–4576, is corrected as follows:

1. On page 12314, column 3, in the preamble, under the paragraph heading ''Comments and Public Hearing'', line 2 of the second paragraph, the language ''for April 11, 2007, at 10 a.m., in the IRS'' is corrected to read ''for April 11, 2008, at 10 a.m., in the IRS''.

2. On page 12314, column 3, in the preamble, under the paragraph heading ''Comments and Public Hearing'', line 8 of the third paragraph, the language ''and eight (8) copies) by March 28, 2007.'' is corrected to read ''and eight (8) copies) by March 28, 2008.''.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E8–5336 Filed 3–17–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–151135–07]

RIN 1545–BH39

Multiemployer Plan Funding Guidance

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations under section 432