originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The FAA is issuing this AD to detect and correct screws of excessive length installed on the ceiling panel covering the aileron control assembly, which could cause the aileron control rod to become jammed, cracked, or damaged. The unsafe condition, if not addressed, could result in unintended jamming of the aileron control assembly, the inability to use the aileron control surfaces, and loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection/Measurement

Before further flight after the effective date of this AD, perform a detailed visual inspection of the aileron control assembly, part number 26–9–1502–000, for cracks and damage (including missing paint, nicks, or scrapes) and measure the length of the screws installed on the ceiling cover panel.

(1) If, during the inspection required by paragraph (g) of this AD, any crack or damage (including missing paint, nicks, or scrapes) is found on the aileron control rod assembly, before further flight, repair using a method approved by the FAA; the European Union Aviation Safety Agency (EASA); or Tecnam's Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(2) If, during the inspection required by paragraph (g) of this AD, any screws installed on the ceiling cover panel do not match the limits specified in paragraph (g)(2)(i) or (ii) of this AD, before further flight, replace that screw with the correct screw identified in paragraph (g)(2)(i) or (ii) of this AD, as applicable.

(i) If blind rivet nuts are installed on the ceiling panel covering the aileron control assembly, then the correct panel screw would be 12mm in length with part number UNI7689–3–12.

(ii) If blind rivet nuts are not installed on the ceiling panel covering the aileron control assembly, then the correct panel screw would be equal to or less than 10mm in length with part number UNI6594–2.9–9.5.

Note to paragraph (g): Tecnam Service Bulletin 574–CS-Edition 1, Revision 3, dated August 1, 2022, contains information related to this subject.

(h) Special Flight Permits

Special flight permits are prohibited.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in § 39.19. In accordance with § 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the International Validation Branch, mail it to the address identified in paragraph (j)(2) of this AD or email to: *9-AVS-AIR-730-AMOC@faa.gov.* If mailing information, also submit information by email. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Additional Information

(1) Refer to EASA AD 2022–0167, dated August 11, 2022, for related information. This EASA AD may be found in the AD docket at *regulations.gov* under Docket No. FAA–2022–1162.

(2) For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, General Aviation & Rotorcraft Section, International Validation Branch, FAA, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; email: *jim.rutherford@faa.gov.*

(3) Service information identified in this AD that is not incorporated by reference is available at Costruzioni Aeronautiche Tecnam S.P.A., Airworthiness Office Via S. D'acquisto 62, 80042 Boscotrecase, Italy; phone: +39 0823 997538; email: *technical.support@tecnam.com;* website: tecnam.com. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (817) 222–5110.

(k) Material Incorporated by Reference

None.

Issued on September 8, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–19934 Filed 9–14–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA–2022–N–1128]

RIN 0910–AI46

Defining Small Number of Animals for Minor Use Determination; Periodic Reassessment

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is revising the ''small number of animals'' definition for dogs and cats in our existing regulation for new animal drugs for minor use or minor species. The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) provides incentives to encourage animal drug sponsors to develop and seek FDA approval of drugs intended for use in minor animal species or for minor uses in major animal species. Congress provided a statutory definition of ''minor use'' that relies on the phrase ''small number of animals'' to characterize such use. We are revising the definition of ''small number of animals'' based on our most recent reassessment of the small numbers, which we conducted from 2018 to 2019.

DATES: This rule is effective December 14, 2022. Either electronic or written comments on this direct final rule or its companion proposed rule must be submitted by November 14, 2022. If FDA receives no significant adverse comments within the specified comment period, the Agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the Agency will publish a document in the **Federal Register** withdrawing this direct final rule within 30 days after the comment period on this direct final rule ends.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 14, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–N–1128 for ''Defining Small Number of Animals for Minor Use Determination; Periodic Reassessment.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Margaret Oeller, Center for Veterinary Medicine (HVF–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0566, email: *margaret.oeller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Direct Final Rule

This direct final rule amends the definition of ''small number of animals'' as it relates to dogs and cats in our regulation implementing the MUMS Act. The term ''minor use'' is 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 occurs in limited geographical areas and in only a small number of animals annually. The ''small number of animals'' definition is used for purposes of determining whether a particular intended use of a drug in one of the seven major species of animals (horses, dogs, cats, cattle, pigs, turkeys, and chickens) qualifies as a minor use. In March 2008, FDA issued a proposed rule to establish the meaning of ''small number of animals'' as that term is used in the definition of minor use included in the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA finalized the rule in August 2009. The definition for the phrase ''small number of animals'' includes a specific upper limit number (*i.e.,* small number) for each of the seven major species of animals.

In response to comments submitted to FDA regarding the 2008 proposed rule, we stated in the final rule that we would periodically reevaluate the small numbers and update the definition if necessary. This direct final rule is the result of our 2018–2019 reassessment of the ''small numbers of animals.''

B. Summary of the Major Provisions of the Direct Final Rule

Based on our 2018–2019 reassessment, we are revising the small number for dogs included in the ''small number of animals'' definition from 70,000 to 80,000 and the small number for cats from 120,000 to 150,000.

C. Legal Authority

The legal authority for this direct final rule is the MUMS Act, which amended the FD&C Act. Additional authority comes from the ''Regulations and Hearings'' section of the FD&C Act, which authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

Sponsors that apply for and receive conditional approval for a new animal drug intended for a ''minor use'' in dogs or cats as a result of the changes to the small numbers made by the direct final rule will be able to market their drug earlier, which in turn could benefit pet owners by improving the health of dogs and cats with uncommon diseases or conditions. Both FDA and those sponsors receiving conditional approval could receive cost savings from deferring costs associated with providing FDA with substantial evidence that a new animal drug is effective until later in the drug development process. ''Substantial evidence'' is the effectiveness standard that must be met before a sponsor can receive full approval for its new animal drug under the FD&C Act. Conditional approval does not require the drug sponsor to demonstrate effectiveness by ''substantial evidence.'' Instead, the sponsor has to show that there is a ''reasonable expectation'' of effectiveness. Sponsors could incur

costs to prepare and submit additional minor use determination requests and annual designation reports to FDA. In addition, FDA will bear costs to review any additional minor use determination requests and annual designation reports it receives from sponsors. FDA estimates that the annualized benefits over 20 years will range from $0 to $6.06 million at a 7 percent discount rate, with a primary estimate of $3.03 million, and from $0 to $7.43 million at a 3 percent discount rate, with a primary estimate of $3.72 million. Annualized costs will range from $3,033 to $31,741 at a 7 percent discount rate, with a primary estimate of $17,387, and from $2,244 to $30,285 at a 3 percent discount rate, with a primary estimate of $16,264.

II. Table of Abbreviations and Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
2013 reassessment	Reassessment of small numbers conducted by FDA in 2013, the results of which were published in May 2014 (79 FR 28736).
AVMA	American Veterinary Medical Association.
21 CFR	Title 21 of the Code of Federal Regulations.
Current reassessment	Reassessment of small numbers conducted by FDA in 2018–2019.
FDA	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
MUMS	Minor Use and Minor Species.
MUMS Act	Minor Use and Minor Species Animal Health Act of 2004.
OMB	Office of Management and Budget.
Pub. L	Public Law.

III. Background

A. Introduction

The MUMS Act (Pub. L. 108–282) amended the FD&C 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 (see section 201(pp) of the FD&C Act (21 U.S.C. 321(pp)). Congress charged FDA to further define the term ''small number of animals'' for minor use purposes (see Senate Report 108–226 at 8, February 18, 2004). In the **Federal Register** of March 18, 2008 (73 FR 14411), we issued a proposed rule to define the term ''small number of animals'' by establishing for each major species of animal (horses, dogs, cats, cattle, pigs, turkeys, and chickens) an upper limit threshold (*i.e.,* small number) to provide a means of determining whether any particular intended use of a new animal drug in one of these species would qualify as a minor use under the MUMS Act.

The ''small numbers of animals'' definition was formally established by the final rule that was published on August 26, 2009 (74 FR 43043). In that final rule, we addressed comments from the public regarding the 2008 proposed rule, including comments suggesting that the Agency reevaluate the small numbers on a periodic basis. We agreed that periodic reassessment of the small numbers is appropriate and that such reassessments should occur approximately every 5 years.

We conducted our initial reassessment of the small numbers in 2013 and published the results of that reassessment on May 19, 2014 (79 FR 28736) (the 2013 reassessment). At that time, we did not change the small numbers for any of the major species.

From 2018 to 2019, we conducted our second reassessment (current reassessment) of the small numbers (Ref. 1). Based on the current reassessment, we are revising (*i.e.,* increasing) the small numbers for dogs and cats only. Elsewhere in this issue of the **Federal Register**, we are publishing a notice to announce that we are not revising the small numbers in the ''small number of animals'' definition for the other major species (*i.e.,* horses, cattle, pigs, turkeys, and chickens). Because we are only revising the ''small number of animals'' definition as it relates to dogs and cats, the remainder of this document will focus on those two species.

B. History of Defining Small Numbers for Dogs and Cats

The term ''small number of animals'' is defined in § 516.3(b) (21 CFR 516.3(b)) of our regulation on new animal drugs for minor use and minor species. For each of the seven major species of animals, the definition specifies the greatest number of animals of that species that could be treated annually with a new animal drug for a particular indication and still qualify as a minor use. For dogs and cats, a ''small number of animals'' is defined as equal to or less than 70,000 dogs, or equal to or less than 120,000 cats.

The process FDA used to establish the small numbers for the companion animal major species (dogs, cats and horses) is outlined in detail in the 2008 proposed rule. That process involved estimating the development cost for an animal drug intended for each of the three major companion animal species, estimating the amount that companion animal owners were willing to pay for a drug to treat each of those species, estimating the average percentage of companion animals that would likely be treated, and estimating the uncertainty associated with estimates of the rate of occurrence of various uncommon conditions in companion animals. Assessment of these various factors resulted in the formula, published in the proposed rule (73 FR 14411 at 14414), that we use to determine the small numbers for companion animals.

C. Need for the Regulatory Action

In the preamble to the 2009 final rule in which we first established the definition of ''small number of animals,'' we agreed in response to comments that we should periodically reevaluate the small numbers and update the definition as necessary. We also agreed that such a reevaluation should take into account the potential for changes in the development cost of new animal drugs, changes in the amount that animal owners are willing to pay to treat affected animals, and changes in other factors involved in establishing a ''small number,'' such as the total population of major animal species (74 FR 43043 at 43044).

In a memorandum containing the results of our current reassessment, we describe the processes that we used to reevaluate the small number of animals (Ref. 1). Based on the current reassessment, we are increasing the small numbers for dogs and cats only.

IV. Legal Authority

We are issuing this direct final rule under the same legal authorities described in the proposed and final rules we issued to establish the ''small number of animals'' definition in 21 CFR part 516 (see 73 FR 14411 at 14415 and 74 FR 43043 at 43049). These authorities include sections 571, 573, and 701 of the FD&C Act (21 U.S.C. 360ccc, 360ccc–2, and 371). Sections 571 and 573 of the FD&C Act were established by the MUMS Act. Section 701(a) authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

V. Description of the Direct Final Rule

A. Revisions to the ''Small Number of Animals'' Definition in § 516.3

As discussed in section III. C, when we published the final rule defining ''small number of animals'' for minor use designation in 2009, we agreed we should periodically reevaluate the small number of animals to account for changes in drug development costs, changes in the amount that animal owners are willing to pay to treat affected animals, and other relevant factors (74 FR 43043 at 43044). Based on our current reassessment (Ref. 1), we are revising the definition of ''small number of animals'' in § 516.3(b) to increase the small number for dogs from 70,000 to 80,000, and to increase the small number for cats from 120,000 to 150,000.

B. Reassessment of the Small Numbers for Dogs and Cats

For our current reassessment of the small numbers, our primary source of information regarding costs related to dogs and cats is a 2018 report prepared by Brakke Consulting Inc., (BCI) containing population estimates, disease incidence rates, and information about drug development costs and treatment costs for companion animals (Ref. 2). The 2018 report is the latest update of the BCI report. We used previous versions of the BCI report for the 2008 proposed rule and the 2013 reassessment. Our primary source of information regarding healthcare costs for dogs and cats is the 2017–2018 edition of the American Veterinary Medical Association (AVMA) U.S. Pet Ownership and Demographics Sourcebook, which contains surveys of pet ownership (Ref. 3). This is an updated version of the same source we used for our 2008 proposed rule and the 2013 reassessment.

After evaluating the relevant data from these sources and using that information to reassess the small numbers for dogs and cats, we determined that the small numbers for dogs and cats should be increased. Therefore, we are revising the definition of ''small numbers of animals'' for these two species. For a full discussion of our current reassessment of the small numbers, see our current reassessment memorandum (Ref. 1).

VI. Direct Final Rulemaking

In the document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures,'' announced in the **Federal Register** of November 21, 1997 (62 FR 62466), FDA describes its procedures on when and how the Agency will employ direct final rulemaking. The guidance may be accessed at: *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm.*

We have determined that the subject of this rulemaking is suitable for a direct final rule. We are revising the ''small number of animals'' definition for dogs and cats in § 516.3(b) to increase the small numbers for these two species. This rule is intended to make noncontroversial changes to an existing regulation. We do not anticipate that there will be any significant adverse comments.

Consistent with our procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule. The companion proposed rule and this direct final rule are substantively identical. The companion proposed rule provides the procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of a significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period for the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this direct final rule.

We are providing a comment period for the direct final rule of 60 days after the date of publication in the **Federal Register**. If we receive a significant adverse comment, we intend to withdraw this direct final rule before its effective date by publishing a notification in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rule, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553).

Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in the direct final rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to a part of this rule and that part can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of the significant adverse comment.

If any significant adverse comment is received during the comment period, we will publish, before the effective date of this direct final rule, a notification of significant adverse comment and withdraw the direct final rule. If we withdraw the direct final rule, any comments received will be applied to the proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedure. If we do not receive any significant adverse comment in response to this direct final rule during the comment period, we will publish a document in the **Federal Register** confirming the effective date of the final rule within 30 days after the comment period ends.

VII. Economic Analysis of Impacts

We have examined the impacts of the direct final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us 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; distributive impacts; and equity). We believe that this direct final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because net costs of the direct final rule are less than 0.32 percent of average annual revenues for the smallest firms

in the industry, we certify that the direct final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''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 $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This direct final rule would not result in an expenditure in any year that meets or exceeds this amount.

By expanding incentives for new animal drug development under the MUMS Act as a result of increasing the small numbers for dogs and cats, the direct final rule could benefit pet owners by improving the health of dogs and cats with uncommon diseases or conditions. These health improvements could result from the earlier marketing of new animal drugs by sponsors that apply for and receive conditional approval as a result of the direct final rule. The direct final rule also could result in cost savings to new animal drug sponsors and FDA. Sponsors that receive conditional approval have the ability to market their new animal drug for up to 5 years, subject to annual renewals, before providing substantial evidence that it is effective, as required for full approval. This would defer costs to sponsors and FDA associated with a demonstration of substantial evidence of effectiveness until later in the development process.

Because the direct final rule could increase the number of uncommon diseases or conditions in dogs and cats that qualify for minor use drug development incentives, including user fee waivers, exclusive marketing rights, grants, and eligibility for conditional approval, sponsors could incur costs to prepare and submit additional minor use determination requests and, for those sponsors that pursue designation for their new animal drug, annual designation reports to FDA. FDA will bear costs to review any additional minor use determination requests and annual designation reports. Potential sponsors of new animal drugs for minor uses in dogs or cats will also incur a one-time cost to read and understand the direct final rule.

We additionally estimate potential within-industry transfers from sponsors receiving user fee waivers as a result of the direct final rule to fee-paying sponsors, and transfers from government to industry in the form of grants to support safety and effectiveness testing.

We summarize the annualized benefits and costs of the rule in table 1. We estimate that the annualized benefits over 20 years will range from $0 to $6.06 million at a 7 percent discount rate, with a primary estimate of $3.03 million, and from $0 to $7.43 million at a 3 percent discount rate, with a primary estimate of $3.72 million. Annualized costs will range from $3,033 to $31,741 at a 7 percent discount rate, with a primary estimate of $17,387, and from $2,244 to $30,285 at a 3 percent discount rate, with a primary estimate of $16,264.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized ($m/year)	$3.03	$0.00	$6.06	2021	7	20	These include benefits to pet owners and cost savings to industry and FDA.
	3.72	0.00	7.43	2021	3	20	
Annualized Quantified							
Qualitative.							
Costs:							
Annualized Monetized ($m/year)	0.017	0.003	0.032	2021	7	20	
	0.016	0.002	0.030	2021	3	20	
Annualized Quantified							
Qualitative.							
Transfers: [1]							
Federal Annualized Monetized ($m/year)	0.43	0.00	0.86	2021	7	20	
	0.48	0.00	0.97	2021	3	20	
	From: Government			To: Industry			
Other Annualized Monetized ($m/year)	0.47	0.00	0.94	2021	7	20	
	0.57	0.00	1.14	2021	3	20	
	From: Industry			To: Industry			

Effects:
State, Local, or Tribal Government: None.
Small Business: Quantified effects of less than 0.32 percent of average annual revenues for the smallest firms.
Wages: None.
Growth: None.

[1] Transfers are monetary payments between persons or groups that do not affect the total resources available to society.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the direct final rule. The full analysis of economic impacts is available in the docket for this direct final rule (Ref. 4) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. Analysis of Environmental Impact

We have 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.

IX. Paperwork Reduction Act of 1995

This direct final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Designated New Animal Drugs for Minor Use and Minor Species; OMB control number 0910–0605—Revision.

Description: The direct final rule revises the ''small number of animals'' definition for dogs and cats in our existing regulation at § 516.3(b) for new animal drugs for minor use and minor species. The small numbers for dogs and cats are increased. The MUMS Act provides incentives to encourage animal drug sponsors to develop and seek FDA approval of drugs intended for use in minor species or for minor uses in major animal species. Congress provided a statutory definition of ''minor use'' that relies on the phrase ''small number of animals'' to characterize such use. The ''small number of animals'' definition is used for purposes of determining whether a particular intended use of a drug in one of the major species of animals qualifies as a minor use.

Description of Respondents: Pharmaceutical companies that sponsor new animal drugs.

We estimate the burden of this information collection as follows:

TABLE 2—ESTIMATED ONE-TIME RECORDKEEPING BURDEN

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Reading and Understanding the Rule	474	1	474	0.683 (41 minutes)	323

Using the number of active sponsors of new animal drug applications and active sponsors of abbreviated new animal drug applications, we estimate there are 237 sponsors affected by this rule. We estimate two recordkeepers per sponsor.

We expect that new animal drug sponsors will incur a one-time burden associated with reading and understanding the rule and a nominal increase in the overall annual burden associated with reporting requirements resulting from a potential increase in submissions of minor use determination requests and annual designation reports to FDA.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection provisions of this direct final rule to OMB for review. Before the effective date of this direct final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove of the information collections of this direct final rule.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

X. Federalism

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the direct final 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, we conclude that the 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.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13175. We have determined that the direct final rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the direct final rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov*. References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

* 1. FDA Memorandum, ''2018–2019 Reassessment of Small Numbers of Animals for Minor Use Determination'', 2021.
* 2. Brakke Consulting, Inc., Update of Population Estimates, Disease Incidence Rates, Drug Development Costs and Treatment Costs for Companion Animals,'' October 22, 2018.
3. American Veterinary Medical Association, ''Pet Ownership and Demographics Sourcebook,'' 2017–2018 Edition, October 2018. Accessed November 09, 2021. *https://www.avma.org/news/press-releases/avma-releases-latest-stats-pet-ownership-and-veterinary-care* and *https://www.avma.org/sites/default/files/resources/AVMA-Pet-Demographics-Executive-Summary.pdf.*
* 4. FDA, ''Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis'', 2021.

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, 21 CFR part 516 is amended as follows:

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

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

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

■ 2. Amend § 516.3(b) by revising the definition for ''Small number of animals'' to read as follows:

§ 516.3 Definitions.

* * * * *

(b) * * *

Small number of animals means equal to or less than 50,000 horses; 80,000 dogs; 150,000 cats; 310,000 cattle; 1,450,000 pigs; 14,000,000 turkeys; and 72,000,000 chickens.

* * * * *

Dated: August 31, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–19954 Filed 9–14–22; 8:45 am]

BILLING CODE 4164–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Allocation of Assets in Single-Employer Plans to prescribe interest assumptions under the asset allocation regulation for plans with valuation dates in the fourth quarter of 2022. These interest assumptions are used for valuing benefits under terminating single-employer plans and for other purposes.

DATES: Effective October 1, 2022.

FOR FURTHER INFORMATION CONTACT: Gregory Katz (*katz.gregory@pbgc.gov*), Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101, 202–229–3829. If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION: PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes actuarial assumptions—including interest assumptions—for valuing benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974 (ERISA). The interest assumptions in the regulation are also published on PBGC's website (*https://www.pbgc.gov*).

PBGC uses the interest assumptions in appendix B to part 4044 (''Interest Rates Used to Value Benefits'') to determine the present value of annuities in an involuntary or distress termination of a single-employer plan under the asset allocation regulation. The assumptions are also used to determine the value of multiemployer plan benefits and certain assets when a plan terminates by mass withdrawal in accordance with PBGC's regulation on Duties of Plan Sponsor Following Mass Withdrawal (29 CFR part 4281).

The fourth quarter 2022 interest assumptions will be 3.90 percent for the first 20 years following the valuation date and 3.65 percent thereafter. In comparison with the interest assumptions in effect for the third quarter of 2022, these interest assumptions represent no change in the select period (the period during which the select rate (the initial rate) applies), an increase of 1.09 percent in the select rate, and an increase of 0.71 percent in the ultimate rate (the final rate).

Need for Immediate Guidance

PBGC has determined that notice of, and public comment on, this rule are impracticable, unnecessary, and contrary to the public interest. PBGC routinely updates the interest assumptions in appendix B of the asset allocation regulation each quarter so that they are available to value benefits. Accordingly, PBGC finds that the public interest is best served by issuing this rule expeditiously, without an opportunity for notice and comment, and that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication to allow the use of the proper assumptions to estimate the value of plan benefits for plans with valuation dates early in the fourth quarter of 2022.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is amended as follows:

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 2. In appendix B to part 4044, an entry for ''October–December 2022'' is added at the end of the table to read as follows:

Appendix B to Part 4044—Interest Rates Used To Value Benefits

* * * * *

For valuation dates occurring in the month—	The values of i_t are:					
	i_t	for t =	i_t	for t =	i_t	for t =
*	*	*	*	*	*	*
October–December 2022	0.0390	1–20	0.0365	>20	N/A	N/A