Property Inventory Maps. FAA Order 5190.6, *Airport Compliance Manual,* will be updated to reflect this policy guidance.

Process for Evaluating Land Use Changes

Uses of airport land will fall into one of four categories: (1) Aeronautical use, (2) Airport Purpose, (3) Non-Aeronautical Use, or (4) Mixed-Use.

FAA must approve or consent to all non-aeronautical and mixed uses of federally acquired and federally conveyed land. If the FAA determines that the proposed use serves an aeronautical use or airport purpose as defined above, then FAA approval or consent is not required. The following explains the process when an airport sponsor requests a change in land use on federally conveyed or federally acquired land:

1. What Sponsors Must Submit

The sponsor's request needs to include the following:

a. documentation on how the land was acquired (*i.e.,* federal conveyance documents, Federal grant agreements, Exhibit A, etc.);

b. current and future aeronautical demand of the airport and the land; and

c. proposed non-aeronautical use, including the length of the lease.

2. FAA's Evaluation of the Request

FAA's determination of whether the non-aeronautical use is significant, consistent with the term ''mixed uses'' in ''Explanation of Terms'' in this document, will be made based on *the primary use of the project.* The process involves a certain level of discretion by the FAA and the airport sponsor. Major considerations in granting approval or consent include:

a. reasonableness and practicality of the sponsor's request,

b. effect of the request on needed aeronautical facilities, and

c. compatibility of the proposal with the needs of civil aviation. (*Note:* The residential use of airport property is incompatible with the needs of civil aviation, is prohibited by FAA policy, and is also contrary to Federal obligations.)

The distinctions may vary slightly depending on the circumstances of the situation, such as intermodal functionality, proponent's business model, project integrity, available airport land, project size and location, airport planning priorities, and funding requirements and restrictions. The proposal must benefit the airport and its functions in support of aeronautical uses and not adversely affect the value of the Federal investment in the airport and its facilities. 49 U.S.C. 47107(a)(16)(B), 49 U.S.C. 47125(a), and 49 U.S.C. 47152(1).

The use should be compatible with the airport's current or future aeronautical use or demand. FAA approval shall not be granted if the FAA determines that an aeronautical demand for the land is likely to exist within the period of the proposed use, or it compromises the safety and operation of the airport. FAA consent to or approval of a non-aeronautical use should only extend for duration of the lease term and must provide that the land will be returned to aeronautical use at the end of the term.

3. Documentation of FAA Decision

Upon completion of the review, the FAA will either issue a letter of approval or letter of consent for the non-aeronautical use or mixed-use, or deny the request.

The letter of approval or letter of consent must document the FAA's approval of a non-aeronautical land use on federally acquired or federally conveyed airport land. This letter will outline the conditions of the approval or consent and include a requirement that the land must be available for aeronautical use at the end of the approval or consent period. Generally, the approval or consent will remain for the duration of the lease agreement. The letter of approval or letter of consent does not affect or negate the sponsor's federal obligations.

The requirement for NEPA should be coordinated with FAA Environmental Protection Specialists.

All land use changes should be shown on the Exhibit A in accordance with ARP SOP 3.00—*FAA Review of Exhibit 'A' Airport Property Inventory Maps.* This includes depicting in a table format the type of use for a facility, (*e.g.*: aeronautical, non-aeronautical, mixed-use), and the approval and expiration dates.

Issued in Washington, DC, on September 7, 2022.

Kevin C. Willis,

Director, Office of Airport Compliance and Management Analysis.

[FR Doc. 2022–19665 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, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to revise 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 proposing certain revisions to 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: Either electronic or written comments on this proposed rule or its companion direct final rule must be submitted by November 14, 2022. Submit written comments (including recommendations) on the collection of information under the Paperwork Reduction Act of 1995 by November 14, 2022. If FDA receives any timely significant adverse comments on the direct final rule with which this proposed rule is associated, the Agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will apply any significant adverse comments received on the direct final rule to the proposed rule in developing the final rule. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

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.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is ''Designated New Animal Drugs for Minor Use and Minor Species.''

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 Proposed Rule

The proposed rule would amend 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 proposed rule is the result of our 2018–2019 reassessment of the ''small numbers of animals.''

B. Summary of the Major Provisions of the Proposed Rule

Based on our 2018–2019 reassessment, we are proposing to revise 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 proposed 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 that would be made by the proposed rule, if finalized, would 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 would 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 would 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 would 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 proposing to revise (*i.e.,* increase) 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 proposing to revise 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 Proposed 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 proposing to increase the small numbers for dogs and cats only.

IV. Legal Authority

We are issuing this proposed 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 Proposed Rule

A. Proposed 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 proposing to revise 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 proposing revisions to 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. Companion Document to 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.*

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. We propose to revise the ''small number of animals'' definition for dogs and cats in § 516.3(b). This proposed 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 direct final rule. The companion direct final rule and this companion proposed rule are substantively identical. This 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 proposed rule runs concurrently with the comment period for the companion direct final rule. Any comments received in response to the companion direct final rule will also be considered as comments regarding this proposed rule.

We are providing a comment period for the proposed rule of 60 days after the date of publication in the **Federal Register**. If we receive a significant adverse comment, we intend to withdraw the direct final rule before its effective date by publishing a notice 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 this proposed rule would not be considered a significant adverse comment unless the comment states why the proposed

rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to a part of this proposed rule and that part can be severed from the remainder of the proposed rule, we may adopt as final those provisions of the proposed 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 the direct final rule, a notice of significant adverse comment and withdraw the direct final rule. If we withdraw the direct final rule, any comments received will be applied to this 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 the direct final rule during the comment period, no further action will be taken related to this proposed rule. Instead, 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. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed 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 proposed 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 proposed rule are less than 0.32 percent of average annual revenues for the smallest firms in the industry, we propose to certify that the proposed 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 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 $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This proposed 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 proposed rule, if finalized, 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 proposed rule, if finalized. The proposed rule, if finalized, 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 proposed rule, if finalized, 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 would 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 would also incur a one-time cost to read and understand the rule.

We additionally estimate potential within-industry transfers from sponsors receiving user fee waivers as a result of the proposed rule, if finalized, 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 proposed rule in table 1. We estimate that the annualized benefits over 20 years would 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 would 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 PROPOSED 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	

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

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Annualized Quantified							
Qualitative.							
Transfers: [1]							
Federal Annualized Monetized ($m/year)	0.43 0.48	0.00 0.00	0.86 0.97	2021 2021	7 3	20 20	
	From: Government			To: Industry			
Other Annualized Monetized ($m/year)	0.47 0.57	0.00 0.00	0.94 1.14	2021 2021	7 3	20 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 Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed 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 proposed 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.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

Description: The proposed rule would revise 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 would be 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 that would be affected by this rule. We estimate two recordkeepers per sponsor.

We expect that new animal drug sponsors would 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.

To ensure that comments on the information collections are received, OMB recommends that written comments be submitted through *www.reginfo.gov* (see **ADDRESSES**). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have 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, we conclude 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.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the proposed 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

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, ''Preliminary Regulatory Impact Analysis, Initial 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, 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 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. 2022–19956 Filed 9–14–22; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2020–0690; FRL–9864–01–OCSPP]

RIN 2070–AB27

Modification of Significant New Uses of Certain Chemical Substances (21–1.M)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to amend the significant new use rules (SNURs) for certain chemical substances identified herein, which were the subject of one or more premanufacture notices (PMNs) and in some cases significant new use notices (SNUNs). This action would amend the SNURs to allow certain new uses reported in the SNUNs or PMNs without additional notification requirements and modify the significant new use notification requirements based on the actions and determinations for the SNUN or PMN submissions or based on the examination of new test data or other information. EPA is proposing these amendments based on our review of new and existing data for the chemical substances.

DATES: Comments must be received on or before October 17, 2022.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0302, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information contact: William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001;