approval, the Patent and Trademark Office received a patent term restoration application for ZIOPTAN (U.S. Patent No. 5,886,035) from Asahi Glass Company Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 19, 2013, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ZIOPTAN represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZIOPTAN is 3,881 days. Of this time, 3,481 days occurred during the testing phase of the regulatory review period, while 400 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* June 28, 2001. The applicant claims June 24, 2001, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 28, 2001, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* January 7, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for ZIOPTAN (NDA 202514) was submitted on January 7, 2011.

3. *The date the application was approved:* February 10, 2012. FDA has verified the applicant's claim that NDA 202514 was approved on February 10, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 18, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 17, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 14, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11517 Filed 5–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0176 (Formerly Docket No. 2008N–0011)]

Defining Small Numbers of Animals for Minor Use Designation; Periodic Reassessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its periodic reassessment for defining the small numbers of animals for minor use in major species.

DATES: Submit either electronic or written comments at any time.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov/.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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:

I. Background

The Minor Use and Minor Species Animal Health Act of 2004 (Pub. L. 108–282) (the MUMS Act), defines the term *minor use* to mean the intended use of a new animal drug in a major species for an indication that occurs infrequently and in only a small number of animals annually, or in limited geographical areas and in only a small number of animals annually (21 U.S.C. 321(pp)). As provided by the MUMS Act, major species of animals are dogs, cats, horses, cattle, pigs, turkeys, and chickens (21 U.S.C. 321(nn). This statutory definition of minor use creates the need for FDA to establish a small number of animals for each of the major species of animals (*small number*). In accordance with the provisions of the MUMS Act, the small number is used to determine whether an intended use of a new animal drug in a major species of animal qualifies as a minor use.

FDA established the small numbers by a final rule published in the **Federal Register** on August 26, 2009 (74 FR 43043). In the preamble for the final rule FDA responded to comments with the following:

''FDA agrees that there is a need to periodically reevaluate the definition of ''small number of animals.'' Because Congress did not establish by statute what a ''small number'' is, it affords FDA the opportunity to periodically reevaluate and update the definition of ''small number'' as necessary. We further agree that such a reevaluation should take into account the potential for increases in the development cost of new animal drugs, but note that it also should take into account potential increases in the cost that animal owners are willing to pay to treat affected animals as well as other factors involved in establishing ''small numbers,'' such as changes in the total population of major animal species.''

This is the first time FDA is reassessing the small numbers.

II. Processes Used to Determine Small Numbers of Animals for Minor Use in Major Species

The process used to establish small numbers of animals in major species of food-producing animals is different from the process used to establish small numbers of companion animals (non-food-producing). The processes FDA uses to establish the small numbers were published in the preamble to the proposed rule (73 FR 14411).

The process for determining small numbers of major food-producing animals is based on the amount of food going to market from sheep. Sheep are used because they were the most consumed minor food-producing species at the time the MUMS Act was passed in 2004. In determining that no limit needed to be set on the number of sheep going to slaughter after being treated with a designated new animal drug, Congress effectively established an upper limit for the quantity of food from the major food-producing species that would likewise not be a concern regarding drug residues and antimicrobial resistance. Therefore, FDA established the small numbers of food-producing animals by determining the number of animals of each major food-producing species that constituted an amount of food (biomass) from these species going to market that is equivalent to the amount of food (biomass) from sheep going to market in 2004.

The process of establishing the small numbers of companion animals involves the following:

- Estimating the development cost for a new animal drug intended for each of the companion animal species.
- Estimating the amount of money that companion animal owners are willing to pay to treat each of their animals.
- Estimating the average percentage of companion animals that are likely to be treated.
- Estimating the uncertainty associated with the reported rate of occurrence of various uncommon conditions in companion animals.

Assessing these various factors results in the following formula, as set forth in the preamble for the proposed rule (73 FR 14414):

[Average companion animal drug development cost in dollars] − ⅓ = [minor use ''going market'' in dollars] ÷ [average drug treatment value in dollars for each species] = [a preliminary small number of animals] × 2 (untreated factor) + 13% (uncertainty factor) + [increase to ''round'' number) = [species-specific ''small number of animals'']

III. Data Sources

A. Food-Producing Animals

The current assessment of small numbers for major food-producing animals is based on the number of sheep and lambs going to market in 2013. These data are obtained from the National Agricultural Statistics Service (NASS) of the U. S. Department of Agriculture (USDA) (Ref. 1).

B. Companion Animals

The data used for the estimates referred to in section II are obtained from several sources. These sources include two publicly available reports from an animal industry consulting firm and several publications from the American Veterinary Medicine Association (AVMA) (Refs. 2, 3, 4, 5, and 6).

C. Population Estimate Data Source

As the determination of small numbers for companion animals is based on the size of the entire U.S. population of companion animals, FDA concluded that we should use a single source of population data for the periodic reassessments. Using a single source of population data for periodic reassessment of the small numbers ensures consistent application of the small numbers over time and among parties requesting minor use determinations.

The AVMA U.S. Pet Ownership & Demographics Sourcebook (AVMA Sourcebook) is a comprehensive and statistically valid survey of approximately 50,000 companion animal owners. The AVMA Sourcebook has used the same survey techniques for many years; this makes the AVMA Sourcebook a consistent source for population information. The AVMA Sourcebook is published every 5 years and can be used as a source of up-to-date population information every time FDA reassesses the small numbers. For these reasons, FDA uses the AVMA Sourcebook as our single source of population data for reassessment of the small numbers. FDA used the 2007 AVMA Sourcebook to define the small numbers established in 2009. The latest AVMA Sourcebook was published in 2012 and provides the estimates of the dog, cat, and horse populations in the United States for the current reassessment of the small numbers.

D. Disease Rate Estimate Data Source

Minor use determinations in major species of companion animals are based on an estimate of the rate of occurrence of a disease or condition in a limited population of a companion animal species. Such estimates are derived from published information, from various databases containing information collected from multiple veterinary practices, from current surveys of veterinary practices conducted by parties requesting a minor use determination, or various combinations of these sources of information. Once an estimate of the rate of occurrence of a disease or condition in a sample population is established, that rate must be extrapolated to the entire population of the major species of companion animals in the United States.

IV. Reassessment

A. Food-Producing Animals

The small numbers for major food-producing animals were established, in large part, based on Congressional concern regarding food safety and a perceived need not to provide an incentive for ''wider use'' of drugs in these animals. An acceptable scope of use for major food-producing animals was determined to be a level consistent with the population of the most common minor food-producing species going to market at the time of passage of the MUMS Act, which was sheep. Data from the USDA show that the amount of sheep and lamb going to market has steadily decreased since the MUMS Act was passed in 2004 (Ref. 1). Since the scope of drug use in major food-producing animals was determined to be acceptable at a level equivalent to a higher level than the current level of marketing of sheep and lamb, we see no reason to revise the currently established small numbers for major food-producing animals.

B. Companion Animals

According to the 2012 AVMA Sourcebook, the population of the major species of companion animals in the United States has decreased since 2007; from about 72.1 million to about 69.9 million dogs, from about 81.7 million to about 74.0 million cats, and from about 7.3 million to about 4.9 million horses (Ref. 6).

The potential effect of these population decreases is at least twofold. The first effect would appear to be a decrease in the potential market for animal drugs for uncommon diseases or conditions in companion animals because there are simply fewer animals to experience such diseases or conditions. However, the data indicate that while there may be fewer companion animals owned in 2012 than in 2007, at least with respect to dogs and cats, these animals are owned by persons more likely to pay for their health care.

The second effect of the population decreases is to make any particular disease or condition more likely to be considered a minor use. For example, if the rate of occurrence of a disease or condition in a sample population of horses is estimated to be 0.7 percent (7 horses per 1000) with +/− 10 percent uncertainty, when extrapolated to a U.S. population of 7.3 million horses, this

rate of occurrence would not represent a small number of horses and the intended use would not be considered a minor use. If, in our example, the population decreases to 4.9 million horses, then 0.7 percent of the horse population would represent a small number of horses and the intended use would be considered a minor use.

The reassessment of the small numbers of companion animals is based on the estimates in section II. Current values for these estimates are based on data obtained from a 2013 survey (Ref. 3). The 2013 survey was conducted by the same source and using the same techniques as the 2005 survey (Ref. 2). Significant changes in the values of these estimates and the relationship between these values could provide a basis for revising the small numbers of animals for major species of companion animals.

Information from these surveys indicates that the development cost for new animal drugs intended for use in companion animals has risen from about $15 million in 2005 to about $20 million in 2013, an increase of about 33 percent (Refs. 2 and 3). Information from these surveys indicates that the cost for the treatment of companion animals has also risen. The rise in treatment cost differs by species, with the greatest increases associated with dogs and horses (about 40 percent and 37 percent, respectively), and the smallest increases associated with cats (about 24 percent). These increases reflect weighted averages (based on approximate sample size of the two surveys) of the amounts paid for routine companion animal health care based on information available in 2005 and 2013 (Refs. 2, 3, 4, 5, and 6). The cost estimates from these surveys reflect routine health care, not the care of uncommon, generally serious or life-threatening conditions of companion animals. However, the increase in the costs for routine health care does show the general willingness of companion animal owners to spend more money for the care of their animals now than in 2009 when the small numbers were established.

In addition, other information indicates that owners who consider their animals to be ''family members'' are generally willing to spend more money for the care of their animals than owners who do not. Based on data from AVMA Sourcebooks (Refs. 4, 5, and 6) CVM calculated that the percentage of dog owners and cat owners who consider their animals to be family members in 2012 rose 24 percent and 14 percent, respectively, since 2007, or 31 percent and 22 percent, respectively, since 2002.

When comparing these data, it appears that the willingness of companion animal owners to pay for their animals' health care has increased by an amount similar to the increase in companion animal drug development cost since the establishment of the small numbers.

While in the case of dogs and horses the increase in the willingness of owners to pay for treatment appears to be greater than the increase in the cost of drug development for those species, the uncertainty associated with these estimates does not permit a determination that the difference in the increases is meaningful. Similarly, while the increase in the willingness of cat owners to pay for treatment appears to be less than the increase in cost of drug development, the uncertainty associated with the estimates does not permit a determination that the difference in the increases is meaningful.

Currently available information does not provide a basis to propose a change in the 50 percent estimate of companion animals likely to be treated or in the 13 percent estimate of the uncertainty routinely associated with estimates of the rates of occurrence of uncommon conditions in these species.

Based on the information in this section, there is no reason to revise the currently established small numbers for companion animals.

V. Usefulness of the Small Numbers Used to Determine Minor Use in Major Species

FDA believes that one way to estimate the usefulness of the small numbers used to determine minor use is to look at the accomplishments of FDA's MUMS program since the small numbers were proposed in March 2008.

Of 56 requests for a determination of minor use in a major species submitted to FDA since March 2008, 42 have been determined to be minor uses involving 29 different conditions in major species.

Of the 58 MUMS designations that have been granted to new animal drugs since March, 2008, 23 have involved minor uses in major species.

Most of the 23 new animal drugs designated for minor use in a major species are indicated for the treatment of neoplastic conditions in companion animals. These neoplastic conditions include sarcoids in horses, functional adrenal tumor, transitional cell carcinoma, mast cell tumor, brain tumors, squamous cell carcinoma, melanoma, mammary carcinoma, and lymphoma in dogs. Indications for treatment of non-neoplastic conditions include the treatment of early onset emesis associated with chemotherapy in dogs, equine recurrent uveitis, repair of diaphyseal fractures in dogs, cattle fever tick eradication, equine protozoal myeloencephalitis, reduction of male aggressive behavior in boars, and prevention of diabetic cataracts in dogs.

Based on this information and communications between FDA and sponsors during the new animal drug development process, FDA believes that the current small numbers are useful for implementing the provisions of the MUMS Act.

Potential sponsors of new animal drugs for minor uses should note the importance of seeking a formal, extended minor use determination from FDA. This can be done by means of a written request for designation to the Office of Minor Use and Minor Species Animal Drug Development. Alternatively, it can be accomplished by a written request to the Director, Office of New Animal Drug Evaluation, for an extended minor use determination, either as a basis for establishing eligibility for conditional approval, or as a basis for full approval. Obtaining such a minor use determination is important because, if due diligence toward approval is maintained, the minor use determination will remain in effect in spite of future changes in small numbers or companion animal populations until the designation terminates or a product is approved in the absence of designation. Requests for certain user fee waivers based on minor use status are made and granted on an annual basis. Without a formal, extended minor use determination, granting of the fee waiver request is subject to the changes in small numbers

VI. Significance of Determinations

While the small numbers will not be revised at this time, FDA concludes periodic reassessment is useful for implementing the provisions of the MUMS Act. FDA also concludes that 5 years between reassessments is an appropriate period of time; therefore, FDA expects the next reassessment to occur in 2018.

Based on the current reassessment, the ''small numbers'' listed in 21 CFR 516.3 will not be revised and will continue to be as follows: 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.

VII. Paperwork Reduction Act of 1995

This reassessment of the small numbers of animals currently established by regulation relates to

previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The relevant collections of information in 21 CFR part 516 have been approved under OMB control number 0910–0032.

VIII. Comments

Interested persons may submit either electronic comments regarding this Notice to *http://www.regulations.gov/* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov/*.

IX. References

1. Sheep and Goats—Sheep and Lamb Inventory by Class, National Agricultural Statistics Service (NASS), U. S. Department of Agriculture (USDA), February 1, 2013.
2. Brakke Consulting, Inc., ''Disease Incidence Rates, Drug Development and Treatment Costs,'' September 2005.
3. Brakke Consulting, Inc., ''Update of Population Estimates, Disease Incidence Rates, Drug Development Costs and Treatment Costs for Companion Animals,'' September 6, 2013.
4. Figures 8, 15, and 27 from U. S. Pet Ownership & Demographics Sourcebook 2002 Edition, reproduced by permission of the American Veterinary Medical Association.
5. Tables 1–5, 1–10, and 1–20 from U. S. Pet Ownership & Demographics Sourcebook 2007 Edition, reproduced by permission of the American Veterinary Medical Association.
6. Tables 1–5, 1–9, 1–10, 1–14, 1–20, 1–24, 2–8, 2–9, 2–22, 2–23, 2–46, and 2–47 from U.S. Pet Ownership & Demographics Sourcebook 2012 Edition, reproduced by permission of the American Veterinary Medical Association.

Dated: May 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11446 Filed 5–16–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Mediterranean DASH Diet.

Date: June 5, 2014.

Time: 5:40 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 2620 Hotel Fisherman's Wharf, 2620 Jones Street, San Francisco, CA 94133.

Contact Person: Jeannette L. Johnson, Ph.D., National Institute on Aging, National Institute of Health, 7201 Wisconsin Avenue, Suite 2c212, Bethesda, MD 20892, 301–402–7705, *JOHNSONJ9@NIA.NIH.GOV*.

Name of Committee: National Institute on Aging Special Emphasis Panel; the Life Outcomes Study (LIFE–OS).

Date: June 27, 2014.

Time: 11:30 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ramesh Vemuri, Ph.D., Chief, Scientific Review Branch, National Institute on Aging, National Institute of Health, 7201 Wisconsin Avenue, Suite 2c-212, Bethesda, MD 20892, 301–402–7700, *rv23r@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 13, 2014.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–11456 Filed 5–16–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Amyloid and Vascular Pathology in AD.

Date: June 18, 2014.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Elaine Lewis, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2C212, MSC–9205, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7707, *elainelewis@nia.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 13, 2014.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–11457 Filed 5–16–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,