TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN—Continued

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Total	.....	.....	.....	.....	61,329

[1] Five percent of establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 that transfuse blood and components and FDA-registered blood establishments (0.05 × 4,059 + 1,706).
[2] Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[3] Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.

Dated: December 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32778 Filed 12–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–1977–N–0019 (formerly 1977N–0230), FDA–1977–N–0014 (formerly 977N–0231), FDA–1977–N–0022 (formerly 1977N–0316), and FDA–1977–N–0224 (formerly 1977N–0317)]

Withdrawal of Notices of Opportunity for a Hearing; Penicillin and Tetracycline Used in Animal Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing two 1977 notices of opportunity for a hearing (NOOH), which proposed to withdraw certain approved uses of penicillin and tetracyclines intended for use in feeds for food-producing animals based in part on microbial food safety concerns.[1] (Refs. 1 and 2) FDA is taking this action, and closing the corresponding dockets, because: FDA is engaging in other ongoing regulatory strategies developed since the publication of the 1977 NOOHs with respect to addressing microbial food safety issues; FDA would update the NOOHs to reflect current data, information, and policies if, in the future, it decides to move forward with withdrawal of the approved uses of the new animal drugs described in the NOOHs; and FDA would need to prioritize any withdrawal proceedings (for example, take into account which withdrawal(s) would likely have the most significant impact on the public health) if, in the future, it decides to seek withdrawal of the approved uses of any new animal drug or class of drugs. FDA is also withdrawing the companion proposed rules to these NOOHs. (Refs. 3 and 4)

DATES: This notice is effective December 22, 2011.

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

FOR FURTHER INFORMATION CONTACT: William Flynn, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–9000, email: *William.flynn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Questions regarding the use of antimicrobial drugs in food-producing animals have been raised and debated for many years. (Ref. 5)[2] Following a report that was issued by the British government in 1969 on the use of antibiotics in veterinary medicine and animal husbandry, known as the ''Swann Report,'' the Commissioner of Food and Drugs established a task force to review the use of antibiotic drugs in animal feeds. The task force, established in 1970, included specialists on infectious diseases and animal science from FDA, the National Institutes of Health, the U.S. Department of Agriculture, and the Centers for Disease Control and Prevention, as well as representatives from universities and industry. The task force identified three primary areas of concern (human health hazard, animal health hazard, and antibiotic effectiveness) and guidelines were established to show whether the use of any antibiotic or antibacterial agent in animal feed presents a hazard to human and animal health. (Refs. 1 and 6) The task force also made certain recommendations concerning restrictions on the use of antibiotic drugs in animal feeds at growth promotion and subtherapeutic levels. (Ref. 6)

In 1972, FDA published the conclusions and recommendations of that task force and proposed to require sponsors to submit specific data for antibiotic drugs in animal feeds intended for subtherapeutic or growth promotion use when such drugs are also used in human clinical medicine. (Ref. 6) In 1973, FDA finalized this proposal in 21 CFR 135.109 (re-codified at 21 CFR 558.15 in 1974).[3] (Refs. 7, 8, and 9) This section provided that FDA would propose to revoke approved uses in animal feed of antibiotic and sulfonamide drugs unless certain data were submitted which satisfactorily addressed the outstanding safety and effectiveness issues.

By 1974, FDA had begun to review the data submitted by the sponsors of the antibiotic products and requested that the National Advisory Food and Drug Committee (NAFDC) review the data and make recommendations on the subtherapeutic uses of penicillin and tetracyclines. A subcommittee (the Antibiotics in Animal Feeds subcommittee) was appointed to work in conjunction with expert consultants to address these issues. With respect to the penicillin-containing drugs, the subcommittee recommended FDA immediately withdraw approval of the subtherapeutic uses of penicillin. The

[1] FDA's approval to withdraw the approved uses of the drugs was based on three statutory grounds: (1) The drugs are not shown to be safe (21 U.S.C. 360b(e)(1)(B)); (2) lack of substantial evidence of effectiveness (21 U.S.C. 360b(e)(1)(C)); and (3) failure to submit required reports (21 U.S.C. 360b(e)(2)(A)).

[2] The term ''antimicrobial'' refers broadly to drugs with activity against a variety of microorganisms including: Bacteria, viruses, fungi, and parasites. Antimicrobial drugs that have specific activity against bacteria are referred to as antibacterial or antibiotic drugs. However, the broader term ''antimicrobial,'' commonly used in reference to drugs with activity against bacteria, is used in this document interchangeably with the terms antibacterial or antibiotic. Antimicrobial resistance is the ability of bacteria or other microbes to resist the effects of a drug. Antimicrobial resistance, as it relates to bacterial organisms, occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to treat bacterial infections. (Ref. 5)

[3] Since that time, portions of 21 CFR 558.15 have been removed because those portions of the regulation were determined to be redundant or obsolete. (See 75 FR 16001, March 31, 2010.)

NAFDC accepted the subcommittee's recommendation and recommended to FDA that it ''immediately withdraw approval for the subtherapeutic uses of penicillin, *i.e.,* growth promotion/feed efficiency, and disease control.'' [4] (Ref. 1) FDA accepted these recommendations. (Ref. 1)

With respect to the tetracycline-containing drugs, the subcommittee recommended that FDA: (1) Discontinue use for growth promotion and/or feed efficiency in all animal species for which effective substitutes are available; (2) permit their use for disease control where effective alternate drugs are unavailable; and (3) control the distribution of the tetracyclines to restrict their use. NAFDC did not accept the subcommittee's first two recommendations, and instead recommended that FDA make no changes in the permitted use of chlortetracycline and oxytetracycline in animal feed. (Ref. 2) The NAFDC did adopt the subcommittee's third recommendation that the addition of the tetracycline in feeds be restricted. (Ref. 2) FDA considered these recommendations and decided to propose withdrawal of approval of subtherapeutic uses of tetracyclines in animal feeds except for those conditions of use for which there are no safe and effective substitutes. (Ref. 2)

This process culminated in the 1977 publication of two NOOHs in the **Federal Register** on proposals by the Bureau of Veterinary Medicine (now Center for Veterinary Medicine) to withdraw all uses of penicillin in animal feed, and all subtherapeutic uses of tetracycline in animal feed except for: (1) Oxytetracyline, as an aid in the control of fowl cholera caused by *Pasteurella multocida* in chickens and infectious synovitis caused by *Mycoplama synoviae* in chickens and turkeys; and (2) chlortetracycline (a) as an aid in the maintenance of weight gains in the presence of respiratory diseases, such as shipping fever, in combination with sulfamethazine in beef cattle, (b) as an aid in the control of infectious synovitis caused by *M. pasteurella* in chickens and turkeys, (c) for the control of active infections of anaplasmosis in beef cattle, and (d) as an aid in reducing the incidence of virbrionic abortion in breeding sheep. (Ref. 1 and 2) [5] These NOOHs were published on August 30, 1977 (penicillin) and October 21, 1977 (tetracycline).

At the same time, FDA also published two companion proposed rules proposing to amend the regulations to delete those provisions referencing the approved penicillin and tetracycline uses that would be affected by a withdrawal. (Refs. 3 and 4) FDA did not withdraw any approved use of penicillin or tetracyclines intended for use in feeds for food-producing animals as a result of these NOOHs, or finalize the proposed companion rules, and some new animal drug approvals for the use of these new animal drugs in feeds for food-producing animals remain in effect.

Although FDA initially granted some hearing requests to provide sponsors with the opportunity to present evidence on the safety of the NOOH products, Congress intervened before any hearing was held, directing FDA to hold in abeyance the implementation of its proposed withdrawal actions pending the outcome of further research related to the use of antibiotics in animal feed. (Refs. 10, 11, and 12)

II. Discussion

At this time, FDA is withdrawing the 1977 NOOHs because: (1) FDA is engaging in other ongoing regulatory strategies developed since the publication of the 1977 NOOHs with respect to addressing microbial food safety issues; (2) FDA would update the NOOHs to reflect current data, information, and policies if, in the future, it decides to move forward with withdrawal of the approved uses of the new animal drugs described in the NOOHs; and (3) FDA would need to prioritize any withdrawal proceedings (for example, take into account which withdrawal(s) would likely have the most significant impact on the public health) if, in the future, it decides to seek withdrawal of the approved uses of any new animal drug or class of drugs.

Although FDA is withdrawing the 1977 NOOHs, FDA remains concerned about the issue of antimicrobial resistance. Today's action should not be interpreted as a sign that FDA no longer has safety concerns or that FDA will not consider re-proposing withdrawal proceedings in the future, if necessary. FDA has not ruled out the prospect of future regulatory action, either with respect to the antimicrobial new animal drugs covered by the 1977 NOOHs or any others. However, as discussed further in this document, FDA intends to focus its efforts for now on the potential for voluntary reform and the promotion of the judicious use of antimicrobials in the interest of public health. Importantly, this strategy leaves open the possibility of pursuing withdrawal proceedings at a later time if FDA's proposed strategy does not yield satisfactory results.

1. FDA Is Engaging in Other Ongoing Regulatory Strategies Developed Since the Publication of the 1977 NOOHs With Respect to Addressing Microbial Food Safety Issues

Since the 1977 NOOHs published, FDA has continued to investigate the safety concerns associated with subtherapeutic uses of antibiotics intended for use in feeds for food-producing animals. As mentioned previously, Congress directed FDA to hold proceedings with respect to the 1977 NOOHs in abeyance and instead to conduct more research on the issues in question. (Ref. 10, 11, and 12) In response, FDA contracted with the National Academy of Sciences (NAS) to conduct a study of the safety issues related to the use of antibiotics in animal feed. (Refs. 5 and 13) In particular, FDA asked the NAS to: (1) Study the human health effects of the subtherapeutic use of penicillin and tetracycline in animal feed; (2) review and analyze published and unpublished epidemiological and other data necessary to assess human health consequences of such use; (3) assess the scientific feasibility of additional epidemiological studies; and (4) make recommendations about additional research needed. (Refs. 5 and 9)

The NAS issued its report in 1980, concluding that a very limited amount of epidemiological research had been completed on either the subtherapeutic or therapeutic use of antimicrobials in animal feeds and that existing data could neither prove nor disprove the postulated hazards to human health from subtherapeutic antimicrobial use in animal feed. (Refs. 5 and 9) The report stated that ''[t]he lack of data linking human illness with subtherapeutic levels of antimicrobials must not be equated with proof that the proposed hazards do not exist. The research necessary to establish and measure a definitive risk has not been conducted and, indeed, may not be possible.'' (Refs. 5 and 13)

In 1984, FDA contracted with the Seattle-King County Health Department to complete a study intended to provide additional information regarding potential public health concerns regarding the use of antimicrobial drugs in animal feed. The study focused on

[4] Generally, FDA no longer considers disease control or prevention to be subtherapeutic uses.

[5] These matters were assigned Docket Numbers 77N–0230 and 77N–0316, respectively. Since the original dockets were opened, FDA started using a different numbering convention. Docket Number 77N–0230 is now Docket Number FDA–1977–N–0019, and Docket Number 77N–0316 is now Docket Number FDA–1977–N–0022.

the relationship between the occurrence of *Salmonella spp.* (*Salmonella*) and *Campylobacter jejuni* (*C. jejuni*) in foods of animal origin and the occurrence of human illness caused by those two organisms. The study report indicated that the bacteria obtained from human cases and those obtained from retail poultry had similar antibiotic susceptibility patterns, including similar levels of resistance to tetracycline. (Refs. 5 and 14)

In 1987, FDA asked the Institute of Medicine to conduct an independent review of the human health risks associated with the subtherapeutic uses of penicillin and tetracycline in animal feed. (Refs. 5 and 15) The IOM established a committee which developed a risk-analysis model using data on *Salmonella* infections that resulted in human death. (Refs. 5 and 15) The Committee did not find a substantial body of direct evidence establishing conclusively the presence of a human health hazard resulting from the use of subtherapeutic concentrations of penicillin and the tetracyclines in animal feeds. (Refs. 5 and 15) Nonetheless, the Committee found a considerable body of indirect evidence implicating both the subtherapeutic and therapeutic use of antimicrobials as a potential human health hazard, and made recommendations for further study of the issue.[6] (Refs. 5 and 15)

During the 1990's, FDA continued to investigate the potential risks associated with the use of antibiotic drugs intended for use in feeds for food-producing animals and how to mitigate risks associated with such use. In 1999, FDA published a concept paper titled, ''Proposed Framework For Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (''Framework Document''). (Ref. 19) Among other things, the Framework Document called for revisions to the pre-approval safety assessment for antimicrobial new animal drugs, and the categorization of antimicrobial drugs based on their importance to human medicine. (Ref. 19)

In 2003, FDA published a final guidance for industry (GFI #152), outlining an approach for conducting a qualitative risk assessment to evaluate human food safety with respect to the potential microbiological effects of antimicrobial new animal drugs on food-borne bacteria of human health concern. (Ref. 20) The importance of a drug for human medical therapy is a key factor to be considered in the evaluation. (Ref. 20) Since 2003, FDA has applied the principles contained in GFI #152 when assessing antimicrobial resistance risks for antimicrobial drugs as part of the new animal drug approval process. In some cases, this has had the effect of limiting the claims for which such drugs are approved while still protecting animal and human health.

Recognizing that already-approved antimicrobial new animal drugs also have antimicrobial resistance risks associated with their use, FDA began to look at the safety of some of these already approved drugs. However, because the process of reviewing safety information for antimicrobial drugs approved before 2003 (and pursuing withdrawal proceedings if appropriate in some cases) would take many years and would impose significant resource demands on the Agency, FDA began thinking about alternate approaches to address safety concerns. As a result, in June 2010 FDA proposed a different strategy to promote the judicious use of medically important antimicrobials in food-producing animals in a draft guidance for industry titled ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals'' (draft GFI #209). (Ref. 5) Generally speaking, judicious uses would be those uses that are appropriate and necessary to maintaining the health of humans and animals.

Draft GFI #209 proposes two principles aimed at ensuring the judicious use of medically important antimicrobials in food-producing animals. The first principle described in the draft guidance is that the use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health. (Ref. 5) As set out in the draft guidance, FDA does not consider production uses of such drugs to be necessary for assuring animal health because, unlike other uses, production uses are not directed at any specifically identified disease, but rather are expressly indicated and used for the purpose of enhancing the production of animal-derived products (*e.g.,* promoting faster weight gain or improving feed efficiency). (Ref. 5) The second principle set out in the draft guidance is that the use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation. (Ref. 5) This principle speaks to the need for the scientific and clinical training of licensed veterinarians to assure that medically important antimicrobials are used in a judicious manner.

Based on feedback the Agency received following the issuance of draft GFI #209, FDA believes that the animal pharmaceutical industry is generally responsive to the prospect of working cooperatively with the Agency to accomplish the principles recommended in draft GFI #209. FDA intends to work with sponsors who approach FDA and are interested in working cooperatively with the Agency to phase out production uses of medically important antimicrobials, and to achieve an orderly transition of medically important antimicrobials currently approved for over-the-counter use in food-producing animals to a marketing status that involves veterinary oversight (*i.e.,* veterinary feed directive (VFD) status for feed use drugs and prescription status for drugs approved for use through other routes of administration).

As part of the proposed strategy, FDA issued an advance notice of proposed rulemaking (ANPRM) on March 29, 2010 (75 FR 15387), to seek public comment on whether and to what extent efficiency improvements should be made to the current VFD process as set forth in FDA's regulation at 21 CFR 558.6. (Ref. 21) FDA received numerous public comments in response to the ANPRM and is taking those comments into account in considering possible revisions to this regulation.

FDA believes that the strategy set out in draft GFI #209 represents another pathway to achieving the same goals contemplated by the 1977 NOOHs, *i.e.,* the judicious use of medically important antimicrobial drugs. FDA believes that by implementing this strategy and proceeding in part under the statutory authority provided under the Animal

[6] FDA's draft guidance titled ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals'' (Draft GFI #209) contains information on additional key studies relevant to this issue. For example, in 1997, the World Health Organization (WHO) issued a report which concluded that all uses of antimicrobials lead to the selection of resistant forms of bacteria and that ''low-level, long-term exposure to antimicrobials may have greater selective potential than short-term, full-dose therapeutic use.'' (Ref. 17) The WHO report contained several recommendations, including a recommendation that the use of antimicrobial drugs for growth promotion in animals be terminated if these drugs are also prescribed for use as anti-infective agents in human medicine or if they are known to induce cross-resistance to antimicrobials used for human medical therapy. (Ref. 17) It also recommended that national practices of antimicrobial use in animals be reviewed, and policies be developed to reduce the risks of selection and dissemination of antimicrobial resistance. (Ref. 17) Further, in 1999 the National Research Council issued a report that, among other things, recommended that further development and use of antibiotics in both human and animal medicine have oversight by an interdisciplinary panel of experts. (Ref. 18)

Drug Availability Act of 1996 (ADAA)[7] to designate drugs as VFD drugs (authority which was not available in 1977), it will achieve its goal of promoting the judicious use of antimicrobial drugs in a more timely and resource-efficient manner than could be accomplished otherwise.[8]

2. FDA Would Update the NOOHs To Reflect Current Data, Information and Policies If, in the Future, it Decides To Move Forward With the Withdrawal of the Approved Uses of the New Animal Drugs Described in the NOOHs

Although FDA is optimistic that its proposed strategy to achieve the judicious use of all medically important antimicrobials, as set out in draft GFI #209, will be successful, it has not foreclosed the possibility of using the withdrawal provisions in the Federal Food, Drug, and Cosmetic Act, if necessary, in the future. This applies not only to the classes of antimicrobial drugs covered by the 1977 NOOHs, but also any other production use claims (*i.e.,* growth promotion/feed efficiency uses) for a medically important antimicrobial new animal drug or class of drugs intended for use in food-producing animals. However, if FDA were to pursue withdrawal of approval of any production use claims, it would first publish a notice in the **Federal Register** giving the sponsor(s) of the affected new animal drug(s) notice of the proposed withdrawal(s) and an opportunity for a hearing.

If, at some future time, FDA decides to proceed with the withdrawal of the production uses of penicillins and tetracyclines intended for use in feeds for food-producing animals that were the subject of the 1977 NOOHs, it would publish a new **Federal Register** notice giving sponsors an opportunity for a hearing on the matter. A new notice would be appropriate for many reasons. First, more than three decades have passed since the original notice appeared in the **Federal Register**. FDA would publish a new **Federal Register** notice to ensure all current sponsors of the approved new animal drugs are properly notified and have an opportunity to request a hearing.

Second, not all uses proposed to be withdrawn in the 1977 NOOHs are still approved. The 1977 NOOH which proposed withdrawal of all penicillin-containing premixes intended for use in animal feed also included the then-approved therapeutic uses of penicillin in feed. The stated grounds for proposing to withdraw approval of the therapeutic uses of the penicillin-containing premixes were that there was not substantial evidence of effectiveness of these products for the claimed therapeutic uses. However, there are no currently approved therapeutic uses of penicillins in animal feed.

Third, the body of scientific information relevant to the use of penicillins and tetracyclines in animal feeds has grown since 1977. If the Agency were to pursue the NOOHs, FDA would need to provide notice to the sponsors that the information available since 1977 would be used to support the proposal to withdraw the approved uses of the drugs.

For example, in the early 1990's FDA began collaborating with other government agencies to track antibiotic resistance in foodborne bacteria through a national public health surveillance system, known as the National Antimicrobial Resistance Monitoring System or ''NARMS,'' established to monitor antimicrobial susceptibility among enteric bacteria from humans, retail meats, and food animals. (Ref. 22) Also, since the 1977 NOOHs published, there have been numerous reports, including those by the National Academy of Sciences (Ref. 13), the Institute of Medicine (Ref. 15), the World Health Organization (Ref. 17), and the National Research Council (Ref. 18), that have reviewed available information and made recommendations. In addition, there have been advances in our understanding of the genetics of resistance (*e.g.,* ways in which bacteria accumulate multiple resistance genes).

Fourth, FDA would need to provide notice regarding which approved uses were the subject of the NOOH. In the past, FDA has referred to ''subtherapeutic'' uses at various times to include: (1) ''Increased rate of gain, disease prevention, etc.'' (Ref. 7); (2) ''any use of an antibacterial drug continuously in feed for longer than 14 days'' (Ref. 23); and (3) ''lower levels than therapeutic levels needed to cure disease.'' (Refs. 1 and 2) FDA's thinking on this issue has evolved over the last three decades, and FDA now generally considers disease control and prevention claims to be judicious uses (in other words, therapeutic uses), especially when the drug is administered at the direction and under the oversight of a licensed veterinarian. (Ref. 5)

3. FDA Would Need To Prioritize Any Withdrawal Proceedings (for Example, Take Into Account Which Withdrawal(s) Would Likely Have the Most Significant Impact on the Public Health) if, in the Future, It Decides To Seek Withdrawal of the Approved Uses of Any New Animal Drug or Class of Drugs

To the extent that FDA decides to move forward with withdrawal proceedings for any medically important antimicrobial drugs intended for use in feeds for food-producing animals, it would need to prioritize which withdrawal(s) to propose first based on various considerations, including which withdrawal(s) would have the most significant impact on the public health. It is possible that FDA would conclude that its judicious use goals would better be achieved by first pursuing withdrawals of drugs other than penicillins and tetracyclines. FDA notes that it would need to conduct such an evaluation regardless of the statutory grounds contemplated for the withdrawal action.

III. Conclusion

At this time, FDA is withdrawing the 1977 NOOHs because: (1) FDA is engaging in other ongoing regulatory strategies developed since the publication of the 1977 NOOHs with respect to addressing microbial food safety issues; (2) FDA would update the NOOHs to reflect current data, information, and policies if, in the future, it decides to move forward with withdrawal of the approved uses of the new animal drugs described in the NOOHs; and (3) FDA would need to prioritize any withdrawal proceedings (for example, take into account which withdrawal(s) would likely have the most significant impact on the public health) if, in the future, it decides to seek withdrawal of the approved uses of any new animal drug or class of drugs.

Although FDA is withdrawing the 1977 NOOHs, FDA continues to view antimicrobial resistance as a significant public health issue. Today's action should not be interpreted as a sign that FDA no longer has safety concerns about the use of medically important antibiotics in food producing animals or

[7] ADAA (Pub. L. 104–250), which was signed into law on October 9, 1996, introduced several amendments to the Federal Food, Drug, and Cosmetic Act that provided FDA with more flexibility in how it regulates animal drugs and animal feeds. One such amendment made by the law was to add a new ''veterinary feed directive'' category of new animal drugs to allow the approval and use of drugs in animal feed on a veterinarian's order while incorporating safeguards to help ensure the safe use of the drug.

[8] FDA's experience with contested, formal withdrawal proceedings is that the process can consume extensive periods of time and significant amounts of Agency resources. For example, when FDA withdrew a class of animal drugs called nitrofurans in 1991, the proceedings took nearly 20 years. In another proceeding, the withdrawal of diethylstilbestrol (''DES'') in animals became final in 1979, 7 years after issuance of an NOOH. More recently, the withdrawal of enrofloxacin for use in poultry took almost 5 years and cost FDA approximately $3.3 million.

that FDA will not consider re-proposing withdrawal proceedings in the future, if necessary. FDA has not ruled out the prospect of future regulatory action, either with respect to the antimicrobial new animal drugs covered by the 1977 NOOHs or any others. However, for now, FDA's efforts will focus on promoting voluntary reform and the judicious use of antimicrobials in the interest of best using the agency's overall resources to protect the public health. Importantly, this strategy leaves open the possibility of pursuing withdrawal proceedings at a later time if FDA's proposed strategy does not yield satisfactory results.

As indicated previously, as part of the withdrawal of the two 1977 NOOHs, the Agency will close their corresponding dockets. However, we encourage interested persons to submit comments to the docket established in connection with draft GFI #209. The docket number associated with draft GFI #209 is FDA–2010–D–0094.

IV. Penicillin and Tetracycline Uses in Animal Feed

FDA is withdrawing the 1977 NOOHs, and the related companion proposed rules, because: (1) FDA is engaging in other ongoing regulatory strategies developed since the publication of the 1977 NOOHs with respect to addressing microbial food safety issues; (2) FDA would update the NOOHs to reflect current data, information, and policies if, in the future, it decides to move forward with withdrawal of the approved uses of the new animal drugs described in the NOOHs; and (3) FDA would need to prioritize any withdrawal proceedings (for example, take into account which withdrawal(s) would likely have the most significant impact on the public health) if, in the future, it decides to seek withdrawal of the approved uses of any new animal drug or class of drugs.

V. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday (except on Federal holidays). We have verified all Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**

1. 42 FR 43772 (August 30, 1977).
2. 42 FR 56264 (October 21, 1977).
3. 42 FR 43770 (August 30, 1977).
4. 42 FR 56254 (October 21, 1977).
5. Draft GFI #209, ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,'' June 28, 2010; *http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf.*
6. 37 FR 2444 (February 1, 1972).
7. 38 FR 9811 (April 20, 1973).
8. 21 CFR 135.109 (revised as of April 1, 1974).
9. 21 CFR 558.15 (revised as of April 1, 1975).
10. H. Rept. 95–1290, ''Agriculture, Rural Development and Related Agencies Appropriation Bill, 1979,'' June 13, 1978.
11. H. Rept. 96–1095, ''Agriculture, Rural Development and Related Agencies Appropriation Bill, 1981,'' June 17, 1980.
12. S. Rept. 97–248, ''Agriculture, Rural Development and Related Agencies Appropriation Bill, 1982,'' October 23 (legislative day, October 14), 1981.
13. National Academy of Sciences/National Research Council, ''The Effects on Human Health of Subtherapeutic Uses of Antimicrobials in Animal Feeds,'' 1980, pp. 53–54.
14. 1984 Seattle-King County Study: ''Surveillance of the Flow of Salmonella and Campylobacter in a Community.''
15. National Academy of Sciences/Institute of Medicine, ''Human Health Risks With the Subtherapeutic Use of Penicillin or Tetracyclines in Animal Feed,'' 1988.
16. 68 FR 47272, 47275 (August 8, 2003).
17. 1997 World Health Organization (WHO) Report, '' The Medical Impact of Antimicrobial Use in Food Animals,'' *http://whqlibdoc.who.int/hq/1997/WHO_EMC_ZOO_97.4.pdf*
18. 1999 National Research Council (NRC) Report: ''The Use of Drugs in Food Animals–Benefits and Risks.''
19. A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals, *http://www/fda/gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm126607.htm.*
20. Final Guidance for Industry #152, ''Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern,'' October 23, 2003.
21. 75 FR 15387 (March 29, 2010).
22. *http://www/fda/gov/AnimalVeterinarySafetyHealth/AntimicrobialResistance/NationalAntimmicrobialResistanceMonitoringSystem/default.htm.*
23. 41 FR 8282 (February 25, 1976).

Dated: December 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32775 Filed 12–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0411]

Bristol-Myers Squibb Co. et al.; Withdrawal of Approval of 70 New Drug Applications and 97 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 8, 2011 (76 FR 33310). The document announced the withdrawal of approval of 70 new drug applications (NDAs) and 97 abbreviated new drug applications (ANDAs) from multiple applicants, effective July 8, 2011. The document indicated that FDA was withdrawing approval of the following three ANDAs after receiving a request from the ANDA holder, A.H. Robins Co., c/o Wyeth Pharmaceuticals, Inc., P.O. Box 8299, Philadelphia, PA 19101–8299: ANDA 086661, DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Elixir; ANDA 086676, DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Tablets; and ANDA 086677, DONNATAL (phenobarbital, hyoscyamine sulfate, atropine sulfate, scopolamine (HBr)) Capsules. Before withdrawal of these ANDAs became effective, PBM Pharmaceuticals, Inc., acquired the rights to the ANDAs and informed FDA that it did not want them withdrawn. Because the basis for withdrawal would have been a request from the ANDA holder and the request was timely withdrawn, the approval of ANDAs 086661, 086676, and 086677 is still in effect.

FOR FURTHER INFORMATION CONTACT: Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993–0002, (301) 796–3601.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011–14164 appearing on page 33310, in the **Federal Register** of Wednesday, June 8, 2011, the following correction is made:

On page 33313, in Table 1, the entries for ANDAs 086661, 086676, and 086677 are removed.