ESTIMATED ANNUAL REPORTING BURDEN—Continued

Burden Element	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Costs
Mail-in Response	200	1	200	0	N/A	N/A
Telephone Followup	800	1	800	0.083	67	$1,118
Responses by Telephone Interview	480	1	480	0.5	240	$4,006
Mail-In Response After Receiving Followup	22	1	22	0	N/A	N/A
Total Burden					1,092	$18,225

There are no capital costs or continuing operating and maintenance costs associated with this survey. These burden estimates include the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. The hour and cost burden estimates were derived from a pretest of nine randomly selected facilities.

Dated: June 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–16970 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0121]

Bayer Corp., et al.; Withdrawal of Approval of 29 NADA's

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 29 new animal drug applications (NADA's). Twenty-four NADA's are held by Bayer Corp., Agriculture Division, Animal Health (formerly Miles, Inc., Agriculture Division, Animal Health Products), three are held by Hubbard Milling Co., and one each is held by Hoffmann-LaRoche, Inc., and Ohmeda, Inc. The firms notified the agency in writing that the animal drug products are not being manufactured or marketed and requested that approval of the applications be withdrawn. In a final rule published elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations by removing the entries which reflect approval of the NADA's.

EFFECTIVE DATE: July 15, 1996.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159.

SUPPLEMENTARY INFORMATION: The sponsors of the applications listed in the table in this document have informed FDA that these animal drug products are not being manufactured or marketed and have requested that FDA withdraw approval of the applications.

NADA no.	Drug name	Sponsor name and address
6–462	Diethylcarbamazine tablets	Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201.
10–540	Calcium disodium edetate injection	Do.
11–380	Diethylcarbamazine powder	Do.
12–054	Protokylol hydrochloride tablets and injection	Do.
12–103	Triamcinolone tablets	Do.
12–392	Triamcinolone injection	Do.
12–598	Disophenol sodium injection	Do.
15–161	Trichlorfon powder	Do.
15–965	Coumaphos Type A medicated article	Do.
30–045	Triamcinolone/neomycin sulfate ointment	Do.
34–394	Niclosamide tablets	Do.
35–263	Styrylpyridinium chloride/diethylcarbamazine (as base) oral liquid.	Do.
45–287	Coumaphos crumbles	Do.
48–645	Tylosin Type A medicated articles (5, 10, 20, and 40 grams per pound).	Hubbard Milling Co., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500.
49–555	Styrylpyridinium chloride/diethylcarbamazine control diet HRH/MSD.	Bayer Corp.
91–628	Diethylcarbamazine citrate syrup	Do.
93–372	Chlortetracycline calcium complex Type A medicated articles.	Hoffmann-LaRoche, Inc., Nutley, NJ 07110.
94–402	Tylosin and sulfamethazine Type A medicated articles	Hubbard Milling Co.
95–078	Trichlorfon oral liquid	Bayer Corp.
96–031	Styrylpyridinium chloride/diethylcarbamazine citrate tablets.	Do.
100–201	Trichlorfon paste	Do.
100–356	Styrylpyridinium chloride/diethylcarbamazine control diet HRH.	Do.
100–670	Niclosamide Type A medicated article	Do.
101–078	Dichlorophene and toluene capsules	Do.
120–327	Diethylcarbamazine chewable tablets	Do.
120–670	Styrylpyridinium, diethylcarbamazine edible tablets	Do.

NADA no.	Drug name	Sponsor name and address
121–291	Enflurane liquid (anesthetic)	Ohmeda, Inc., Pharmaceutical Products Division, P.O. Box 804, Liberty Corner, NJ 07938–0804.
121–813	Styrylpyridinium, diethylcarbamazine film-coated tablets	Bayer Corp.
133–509	Pyrantel tartrate Type A medicated articles	Hubbard Milling Co.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA's 6–462, 10–540, 11–380, 12–054, 12–103, 12–392, 12–598, 15–161, 15–965, 30–045, 34–394, 35–263, 45–287, 48–645, 49–555, 91–628, 93–372, 94–402, 95–078, 96–031, 100–201, 100–356, 100–670, 101–078, 120–327, 120–670, 121–291, 121–813, and 133–509, and all supplements and amendments thereto is hereby withdrawn, effective July 15, 1996.

In a final rule published elsewhere in this issue of the Federal Register, FDA is removing 21 CFR 520.500, 520.620a, 520.620b, 520.1520, 520.2022, 520.2160a, 520.2160b, 520.2160c, 520.2160d, 520.2480, 520.2520c, 520.2520d, 522.281, 522.740, 522.2022, 522.2480, 529.810, 558.367, and 558.565, and amending 21 CFR 520.580, 520.622a, 520.622b, 520.2520a, 558.185, 558.485, 558.625, and 558.630 to reflect the withdrawal of approval of the above mentioned NADA's.

Dated: June 3,1996.

Michael J. Blackwell,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 96–16887 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96D–0159]

Compounding of Drugs for Use in Animals; Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Compliance Policy Guide (CPG) section 608.400 entitled ''Compounding of Drugs for Use in Animals.'' The purpose of this CPG is to provide guidance to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists for use in animals. The CPG contains information that may be useful to industry and the public. The text of the CPG is included in this notice. This CPG does not bind FDA, nor does it create or confer any rights, privileges, benefits, or immunities on or for any person.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of CPG section 608.400 entitled ''Compounding of Drugs for Use in Animals'' to the Industry Information Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on CPG section 608.400 entitled ''Compounding of Drugs for Use in Animals'' to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of CPG section 608.400 and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Richard E. Geyer, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1764.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of CPG section 608.400 entitled ''Compounding of Drugs for Use in Animals.'' The purpose of this CPG is to provide clear policy and regulatory guidelines to FDA's field and headquarters staff with regard to the compounding of animal drugs by veterinarians and pharmacists for use in animals. It also contains information that may be useful to industry and to the public.

The Federal Food, Drug, and Cosmetic Act (the act) does not distinguish compounding from manufacturing or other processing of drugs for use in animals. However, veterinarians and pharmacists do manipulate drugs (e.g., combine or dilute finished dosage forms, prepare finished dosage forms from bulk drug substances, or prepare injectables from powdered oral dosage forms) to obtain products that differ from the starting materials.

FDA acknowledges the use of compounding within certain areas of veterinary practice. The current state of veterinary medicine requires products to treat many conditions in a number of different species, some of which are known to have unique physiological characteristics. While the agency acknowledges the need for compounding under certain circumstances, it is also aware of recent adverse reactions and animal deaths caused by compounded drug products and is concerned about the risks associated with compounding practices in veterinary medicine. In addition, the agency is greatly concerned about pharmacies that produce large quantities of unapproved new animal drugs that are essentially copies of FDA-approved products. These pharmacy products are actively advertised and promoted, and sometimes are priced lower than the approved product. The firms claim that they are practicing within the scope of their State licenses. However, it is apparent that some of these firms use their pharmacy licenses to circumvent the entire drug approval process, and are mass marketing products that have been produced under little or no quality control, manufacturing standards to ensure purity, potency, and stability.

When the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) is implemented and becomes effective, it will allow compounding from approved drugs because it will permit the extralabel use of approved animal and human drugs. Extralabel use, including compounding, under AMDUCA will be subject to conditions specified by the implementing regulations. The scope of compounding made legal upon the effective date of AMDUCA will be addressed by those regulations.

CPG section 608.400 represents FDA's current position and interpretation of the act. The CPG is intended to provide clear guidance to FDA field and headquarters staff and also could