Dated: August 28, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20578 Filed 9–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0474] (formerly Docket No. 2005N–0210)

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 6, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0363. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Veterinary Feed Directive—21 CFR Part 558 (OMB Control Number 0910–0363)—Extension

With passage of the Animal Drug Availability Act, Congress enacted legislation establishing a new class of restricted feed use drugs called Veterinary Feed Directive (VFD) drugs. The VFD class of drugs may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to controls for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 503(f)), the implementing VFD regulation under section 558.6 (21 CFR 558.6) is tailored to the unique circumstances relating to the distribution of medicated feeds. The content of the VFD is spelled out in the regulation. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute, and the distribution records of all medicated feeds containing VFD must be maintained. The VFD regulation ensures the protection of the public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

In the **Federal Register** of June 5, 2008 (73 FR 32029), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	300	1	300	.25	75
558.6(d)(1)(iv)	20	1	20	.25	5
558.6(d)(2)	1,000	5	5,000	.25	1,250
514..1(b)(9)	1	1	1	3.00	3
Total	16,321				95,083

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	.0167	6,263
Total	117,500				25,051

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 28, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20579 Filed 9–4–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0448]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Gamma-hydroxybutyric acid; Ketamine; Dextromethorphan; N-benzylpiperazine; 1-(3-trifluoromethylphenyl)piperazine; 1-(3-chlorophenyl)piperazine; 1-(4-Methoxyphenyl)piperazine; 1-(3,4-methylenedioxybenzyl)piperazine; Gamma-butyrolactone; 1,4-Butanediol

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments concerning abuse potential, actual abuse, medical usefulness, trafficking, and impact of scheduling changes on availability for medical use of 10 drug substances. These comments will be considered in preparing the United States' response to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drugs. This notice requesting comments is required by the Controlled Substances Act (CSA).

DATES: Submit written or electronic comments by October 6, 2008.

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

FOR FURTHER INFORMATION CONTACT: James R. Hunter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5146, Silver Spring, MD 20993-0002, 301 796–3156, e-mail: *james.hunter@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The United States is a party to the 1971 Convention on Psychotropic Substances (the Psychotropic Convention). Article 2 of the Psychotropic Convention provides that if a party to the convention or WHO has information about a substance, which in its opinion may require international control or change in such control, it should notify the Secretary General of the United Nations (the Secretary-General) and provide the Secretary-General with information in support of its opinion.

The CSA (21 U.S.C. 811 *et seq.*) (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970) provides that when WHO notifies the United States under Article 2 of the Psychotropic Convention that it has information that may justify: (1) Adding a drug or other substances to one of the schedules of the convention, (2) transferring a drug or substance from one schedule to another, or (3) deleting it from the schedules, the Secretary of State must transmit the notice to the Secretary of Health and Human Services (the Secretary of HHS). The Secretary of HHS must then publish the notice in the **Federal Register** and provide opportunity for interested persons to submit comments that HHS will consider in its preparation of the scientific and medical evaluations of the drug or substance.

I. WHO Notification

The Secretary of HHS received the following notices from WHO:

Ref.: C.L.16.2008

WHO Questionnaire for Collection of Information for Review of Dependence-Producing Psychoactive Substances

The World Health Organization presents its compliments and has the pleasure of informing Member States and Associate Members that the Thirty-fifth Expert Committee on Drug Dependence will meet from 20 to 23 April 2009 to review the following substances:

1. Gamma-hydroxybutyric acid (GHB)
2. Ketamine INN
3. Dextromethorphan pINN
4. N-benzylpiperazine (BZP)
5. 1-(3-trifluoromethylphenyl)piperazine (TFMPP)
6. 1-(3-chlorophenyl)piperazine (mCPP)
7. 1-(4-Methoxyphenyl)piperazine (MeOPP)
8. 1-(3,4-methylenedioxybenzyl)piperazine (MDBP)
9. Gamma-butyrolactone
10. 1,4-Butanediol

One of the essential elements of the established review procedure is for the Secretariat to collect relevant information from Member States to prepare a Critical Review Report for submission to the Expert Committee on Drug Dependence. The World Health Organization invites Member States to collaborate, as in the past, in this process by providing pertinent information mentioned in the attached questionnaire concerning substances listed above.

Further clarification on any of the above items can be obtained from Quality Assurance and Safety: Medicines, Department of Medicines Policy and Standards, WHO, Geneva, to which replies should be sent not later than 20 September 2008.

The World Health Organization takes this opportunity to renew to Member States and Associate Members the assurance of its highest consideration.

GENEVA, 28 May 2008

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If statistical information requested is not readily available, a brief descriptive answer would be appreciated.

Please attach copies of relevant study reports and other background information as appropriate.

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1. GAMMA-HYDROXYBUTYRIC ACID (GHB)

1. LEGITIMATE USE OF THE SUBSTANCE

1.1 Is the substance currently authorized as a medical or veterinary product? (Yes/No)

1.2 If ''yes,'' since when has it been on the market?

1.3 Please indicate registered indications alphabetically.

1.4 Please indicate known off-label medical indications for which the substance is also used in your country.

1.5 Please indicate dosage form(s) and strength(s); also indicate special properties like slow release, etc.

Dosage Form	Strength	Remark