DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS 1880/1882, CMS 10142 and CMS 10036]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* The Request for Certification as a Supplier of Portable X–Ray Services and Portable X–Ray Survey Report Form under the Medicare and Medicaid Program—Portable X–Ray Survey Report and Supporting Regulations under 42 CFR 486.100–486.110; *Form Number:* CMS–1880/1882 (OMB#: 0938–0027); *Use:* The Medicare program requires portable X-ray suppliers to be surveyed for health and safety standards. The CMS–1882 is the survey form that records survey results. The CMS–1880 is used by the surveyor to determine if a portable X-ray applicant meets the eligibility requirements. This information serves as a screen for the State survey agency to determine if the portable X-ray supplier has the basic capabilities to participate in the Medicare program. CMS will use this information to make certification decisions; *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 655; *Total Annual Responses:* 98; *Total Annual Hours:* 172.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage and Prescription Drug Plans (PDP) contained in 42 Code of Federal Regulation (CFR): 422.250, 422.252, 422.254, 422.256, 422.258, 422.262, 422.264, 422.266, 422.270, 422.300, 422.304, 422.306, 422.308, 422.310, 422.312, 422.314, 422.316, 422.318, 422.320, 422.322, 422.324, 423.251, 423.258, 423.265, 423.272, 423.279, 423.286, 423.293, 423.301, 423.308, 423.315, 423.322, 423.329, 423.336, 423.343, 423.346, 423.350; *Form Number:* CMS–10142 (OMB#: 0938–0944); *Use:* Under the Medicare Modernization Act, Medicare Advantage Organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing bid to CMS for approval. The BPT software is used by MAOs and PDPs to price their plan benefit package. The BPT software is used by CMS to review and approve the plan pricing proposed by each organization; *Frequency:* Reporting—On occasion, Annually and As required by new legislation; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 350; *Total Annual Responses:* 350; *Total Annual Hours:* 12,050.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Inpatient Rehabilitation Assessment Instrument and Data Set for Prospective Payment System for Inpatient Rehabilitation Facilities and Supporting Regulations in 42 CFR Sections 412.23, 412.604, 412.606, 412.610, 412.614, 412.618, 412.626, 413.64; *Form Number:* CMS–10036 (OMB#: 0938–0842); *Use:* This is a request to use the Inpatient Rehabilitation Facilities-Patient Assessment Instrument (IRF–PAI) and its supporting manual for the implementation phase of the Inpatient Rehabilitation) Prospective Payment System (PPS). This payment system is to cover both operating and capital costs for inpatient rehabilitation hospital services. It will apply to rehabilitation units of acute care hospitals as well as to rehabilitation hospitals, both of which are exempt from the current Inpatient PPS which is generally applicable for inpatient hospital services. Use of this instrument will enable CMS to implement a classification and payment system for the legislatively mandated inpatient rehabilitation hospital and the aforementioned exempt units. *Frequency:* Recordkeeping, Third party disclosure and Reporting—On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,165; *Total Annual Responses:* 390,000; *Total Annual Hours:* 421,939.

To obtain copies of the supporting statement and any related forms for these paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/regulations/pra/,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB Desk Officer at the address below, no later than 5 p.m. on January 17, 2006.

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 9, 2005.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 05–24112 Filed 12–15–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0273]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Research Study Complaint Form

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 January 17, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being

accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Research Study Complaint Form

Currently, FDA's Center for Drug Evaluation and Research, Division of Scientific Investigations (DSI), receives an average of about 150 unsolicited complaints per year about scientific misconduct in clinical research regulated by FDA through electronic mail, regular mail, phone, and personal contacts. DSI will continue to receive and process such complaints. The internet-based complaint form for consumer complaints on research studies will provide an additional convenient and efficient way for the public to submit complaints regarding misconduct in clinical research regulated by FDA. The complaint form asks questions about the individual, company, or organization that is the subject of the complaint, the event and the drug product(s) that prompted the complaint, and optional information about the person submitting the complaint. The complaint form will be accessible at *http://didit.devis.com/complaints* (username: public; password: fdapublic).

FDA will use the information collected through the complaint form to identify inadequacies in the current services and practices involving human subjects in clinical research and to improve and maintain high quality of services and practices for the affected public. The complaint form will be encrypted so that any information of a sensitive nature will not be unnecessarily or prematurely disclosed. The complaints will remain anonymous unless the complainant voluntarily discloses their identity. Participation is fully voluntary, and complainants will be able to complete, review, edit, and submit the form directly to the FDA. DSI will acknowledge the receipt of each complaint.

Initial analyses by DSI of the information from each complaint will be completed within 10 working days. Each complaint will be reviewed by a responsible person in DSI and then distributed to the appropriate unit in DSI or FDA for further action. DSI will contact the complainant if the complainant requests a followup contact. If the complainant does not request any followup contact, then no additional contact with the complainant is anticipated.

FDA estimates that approximately 144 persons will voluntarily complete the complaint form each year. The estimated time for completing each complaint form will be one hour, resulting in a total burden of 144 hours per year (144 complainants x 1 hour = 144 burden hours per year). The burden of this collection of information is estimated as follows:

TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN[1]

Number of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
144	1	144	1	144

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

In the **Federal Register** of June 30, 2003 (68 FR 38711), FDA requested comments on this information collection. FDA received 3 comments.

(Comment 1) One comment stated that the collection of information is not necessary for the proper performance of FDA's functions. The comment noted that FDA states that it currently receives 150 complaints per year related to alleged scientific misconduct in clinical research via e-mail, mail, and personal contacts, and will continue to accept complaints via these routes. The comment stated that the current system by which FDA accepts complaints spontaneously appears effective and that an additional route is not needed. The comment discouraged the use of an Internet form through which very few complaints may be expected to be filed. The comment stated that it is neither clear that an Internet collection would offer any advantage over existing routes, nor is it clear that it will facilitate the filing of complaints.

(Response) FDA initiates investigations to detect fraud and noncompliance in clinical research based on the complaints it receives. These investigations help FDA to assure that clinical research data submitted to the agency is truthful and accurate and, thereby, help FDA to protect the public by assuring the safety and efficacy of human drugs and biological products. Although the current system of receiving complaints via e-mail, mail, and personal contact, are effective, FDA is constantly attempting to improve its effectiveness by using innovative ideas and processes. Ease of access to an Internet-based complaint form, ability to submit complaints anonymously, and the ability to provide responses to pertinent and standard questions listed on the complaint form offer advantages over the current processes of collecting complaints. It is not possible to predict how many complaints will be submitted to FDA using the Internet-based complaint form. Once the Internet-based complaint form becomes available to the public and the public finds the form easy to use, FDA hopes that the form will become a much more standard means for the public to submit complaints that pertain to FDA-regulated research. The increased use of the Internet-based form will also relieve FDA staff from the time-consuming process of personally documenting each complaint.

The comment also noted that FDA estimates it will take respondents 1 hour to complete the form. The comment stated that while this estimate is reasonable, it may take longer for respondents to locate the form on the Internet. The comment stated that it is not obvious on which Web site(s) the form will appear (e.g., National Institutes of Health (NIH) clinical trial sites, HHS Web site (*http://www.hhs.gov*), FDA Web site(*http://www.fda.gov*)) and how easy it will be to locate.

(Response) The public will be able to access the Internet-based complaint form on the home page of DSI's Web site. The DSI Web site is accessible to the public at *http://www.fda.gov/cder/offices/dsi*. This Web site will include a prominent and direct link to the Internet-based complaint form, which will provide easy access and use of the complaint form. The location of the

complaint form will also be publicized through presentations made by DSI staff at seminars and conferences.

The comment stated that an ad hoc reporting of complaints offers a superior collection mechanism because it allows complaining parties to report alleged misconduct without steering the information offered by a form. The existing collections of information via phone, e-mail, fax, and mail are proven alternatives.

(Response) The complaint form is not intended to direct the complainant's answer. The form may help the complainant to provide more pertinent information to the agency than he/she might otherwise provide. Each complainant will voluntarily submit the complaint. The complainant has the option of providing as much information as desired. There are only two questions on the complaint form that must be answered: (1) Who is the complaint about? and (2) What is the complaint about? If the complainant does not know the answer to any other question in the complaint form, or if the complainant does not wish to provide any additional information, the complainant may leave blank (unanswered) the space following each question. FDA notes that the existing methods of collecting complaint-related information often result in incomplete information and hence should not be assumed to be an existing proven alternative.

The comment stated that if the Internet-based complaint form is used, it should be revised to improve the quality, utility, and clarity of the information to be collected as follows: The form should provide FDA with minimal information upon which to investigate a complaint. To this end, the form should be designed to facilitate its completion with readily available information. It may be unlikely that the reporter has the protocol number and full study title readily available.

(Response) The complaint form has been revised to only obtain minimal information that would be sufficient to facilitate an FDA investigation. As mentioned previously in this document, there are only two questions on the complaint form that must be answered: (1) Who is the complaint about? and (2) What is the complaint about? If the complainant does not know the answer to any other question in the complaint form, or if the complainant does not wish to provide any additional information, the complainant may leave blank (unanswered) the space following each question. If the complainant is aware of study-specific information such as a protocol number and study title, they will have the option of providing such details in the complaint form. Hence, a complainant will have the option of only providing information that is readily available.

The comment stated that the form should be accompanied by the following: (1) An introduction to the form, (2) an explanation as to how it is to be used, and (3) by instructions for its completion.

(Response) The introduction to the complaint form has been revised to read as follows:

DSI COMPLAINT FORM

If you wish to report adverse events (adverse effects or adverse reactions) to drugs or report (medical) product problems, contact MedWatch.

If your complaint is about a research study, please complete this form.

The purpose of this form is for collecting information about the potential scientific or research misconduct, or questionable research practices, involving the use of an FDA regulated drug product.

You must answer the following two questions: (1) Who are you complaining about? and, (2) What is your complaint? If you do not know the answer to any other question in the complaint form, or if you do not wish to provide any additional information, you may leave a blank (unanswered) space following each question.

WHO ARE YOU COMPLAINING ABOUT?

Please provide as much information as possible in this section. You must provide the name of a person, company, or organization about whom you are complaining. If you do not know the answer to any other question, or if you do not wish to provide any additional information, you may leave a blank (unanswered) space following each question.

Name of Person, Company, or Organization: (Required Information)

In addition, under the Complaint Information section, the following change will be made to the first question:

What is your complaint? (Required Information)

The comment stated that the form could be improved by reordering the sections so that they appear in the following order: (1) Reporter Information, (2) Complaint Description, and (3) Organization About Which Complaint Refers.

(Response) FDA has organized the sections based on the order of the importance of the information required for investigating a complaint. Hence, they appear in the following order: (1) The Organization That Is the Subject of the Complaint, (2) The Complaint Description, and (3) Reporter Information (which is optional).

The comment stated that although the **Federal Register** notice states that FDA will contact the complainant if the complainant requests a followup contact, the form lacks this question.

(Response) The optional reporter information section begins with the question ''May the FDA contact you for more information?'' If the answer is yes, the next question is ''How may we contact you? If by phone, please suggest times that are convenient for you.''

The comment stated that the form should use terms and explanations easily understood by the public at no more than a sixth grade reading level. Terms like ''bioequivalence,'' ''sponsor,'' and ''monitor'' should be avoided as they are not widely known except by persons associated with pharmaceutical development.

(Response) The complaint form was designed for the general public to understand. Terms like ''bioequivalence,'' ''sponsor,'' and ''monitor'' will not be understood by everyone, but an individual who does not see a familiar radio-button to select can go to the field titled ''other'' and type the information as they know it.

The comment stated that asking complaining parties to identify other study subjects does not seem consistent with the increased protections being afforded to the privacy of research subjects.

(Response) Requesting complainants to identify other persons (subjects or staff) whom they already know, and who may be able to provide corroborating information pertaining to a complaint, is consistent with current practice. It is also important to note that the complainant is not always a study subject, and the names identified could include study personnel who were involved in the studies under complaint and who may be willing to provide information. In addition, it is important to note that FDA is able to review and copy the records of subjects in studies regulated by FDA. When there is sufficient reason to suspect the validity of data pertaining to specific subjects involved in research, FDA obtains the names of study subjects.

After reviewing this section of the complaint form, FDA has revised the form to note that complainants should also be requested to provide any available contact information regarding those persons they identify as having the potential for providing additional complaint-related information. The complaint form question has been revised to read as follows: ''If you know the name(s) of other persons (subjects or

staff) who were involved in the study(ies), or anyone else who is willing to voluntarily provide information, please list them and include any available contact information (e.g. phone number, fax number, email address, mailing address, etc.).''

Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) and the Bioresearch Monitoring (BIMO) regulations at 21 CFR 812.145(b), 21 CFR 312.68, and 21 CFR 56.115(b), permit FDA investigators at reasonable times to have access to, copy, and verify records. In addition, the subjects' informed consent forms are to include ''a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records'' (21 CFR 50.25(a)(5)). The disclosure of this information to FDA would be consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the Health and Human Service's (HHS') implementing regulation on Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule). HIPAA and the Privacy Rule only apply to covered entities (i.e., health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions for which the Secretary of HHS has adopted standards under HIPAA). As such, many complainants would not be covered by the Privacy Rule. Covered entities may use or disclose protected health information (as defined in 45 CFR 164.501), without a written authorization, as specified in the Privacy Rule. For example, a covered entity may use or disclose protected health information to the extent such use or disclosure is required by law (45 CFR 164.512(a)). A covered entity may disclose protected health information to a public health authority authorized by law to collect or receive such information for the purposes (among others) of conducting public health surveillance, public health investigations, and public health interventions (45 CFR 164.512(b)(1)(i)). In addition, a covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law including audits, investigations, and inspections (45 CFR 164.512(d)). Accordingly, complainants (who are also covered entities) could submit the complaint form to FDA consistent with the Privacy Rule.

The comment stated that although the consent form for a clinical trial should indicate the number of subjects planned for enrollment, it seems unlikely that any one subject would know how many subjects were actually enrolled.

(Response) If a complainant does not know ''how many subjects were enrolled in the study(ies),'' they need not record any information in that field on the complaint form. It is important to note that the complainant is not always a study subject. Sometimes, study coordinators or monitors who are familiar with the number of subjects enrolled in a study may submit the complaint.

The comment objected to complainants being given the option to report anonymously. The comment stated that complainants should be willing to identify themselves to FDA and should be assured that their identities will not be disclosed.

(Response) FDA currently receives several anonymous complaints among the 150 complaints that it receives (via mail and phone contacts) each year regarding alleged scientific misconduct in clinical research. The complaint form does provide complainants the option to reveal their identity. However, FDA believes that complainants should also have the option to remain anonymous. Although FDA makes a good faith effort to protect the identities of complainants, no assurance can be given to complainants that their identity will never be disclosed. It is also important to note that the complainant is not always a study subject. Sometimes, study coordinators or monitors may submit the complaint and would like to remain anonymous for fear of retribution or retaliation.

The comment stated that although the use of an Internet-based form would appear to simplify the collection of complaints, the form as currently proposed would not do so. FDA would need to publicize the availability of the form, explain its intent, revise the form's content, and provide instructions for the form's completion in order to make the Internet-based form a viable addition to existing routes through which complaints are currently captured.

(Response) As mentioned previously in this document, FDA believes that the Internet-based complaint form will simplify the collection of complaints. In addition, work is in progress to automate the data transfer from valid complaint forms into a complaint database, which would save personnel resources that would otherwise be needed to manually record and track complaints. In addition, the automation would reduce the potential for transcription errors and enhance DSI's ability to track complaints. FDA will publicize the availability of the Internet-based complaint form, explain its intent, revise the form's content as necessary, and provide instructions for the form's completion in order to make the Internet-based complaint form a viable addition to existing routes through which complaints are currently captured. It is FDA's intention that the Internet-based complaint form will minimize the paperwork burden for complainants, minimize the cost to the Federal government of the collection, maintenance, use, and disposition of information, and ensure that information technology is used to improve performance of agency missions, including the reduction of information collection burdens on the public.

(Comment 2) A second comment suggested that we change the introductory statement from ''If you wish to report side effects to drugs or other medical products * * *'' to ''If you wish to report adverse reactions or medical product problems contact MEDWATCH.'' The comment stated that MEDWATCH is an adverse event and product problem reporting system, and is typically not used to report side effects that are listed in the product's labeling but rather report serious adverse events not included in the labeling or minimally described in the labeling.

(Response) The introduction to the complaint form has been revised as follows to state: ''If you wish to report adverse events (adverse effects or adverse reactions) to drugs or report (medical) product problems contact MedWatch.''

The comment recommended that the introduction to the form include a statement about the purpose of the form e.g., ''the purpose of this form is for the agency to collect important information about the potential scientific or research misconduct, or questionable research practices, involving the use of an FDA-regulated product.'' The comment stated that without this disclaimer, FDA will likely obtain irrelevant information that is not under FDA, specifically BIMO, purview.

(Response) The following statement of purpose has been added to the introduction in order to obtain more specific information: ''The purpose of this form is for collecting information about potential scientific or research misconduct, or questionable research practices, involving the use of a FDA regulated drug product.''

The comment suggested inserting an e-mail address field.

(Response) The complaint form as designed does provide a field for the complainant to provide an e-mail address. FDA has revised the form to add an option for a complainant to provide the email address of the person they are complaining about.

The comment asked whether FDA had a specific interest in collecting information about coinvestigators or subinvestigators.

(Response) FDA is interested in collecting complaints about subinvestigators and study personnel involved in the conduct of clinical investigations, and the complaint form provides the option for a complainant to provide ''Other'' information about persons or entities that are not specifically included as data fields with radio-buttons. Hence, there would be no need for adding additional radio-buttons for coinvestigators or subinvestigators.

The comment suggested using ''Clinical Study Site'' to be more clear.

(Response) The complaint form will be revised to replace the use of ''Clinical Site'' with ''Clinical Study Site''. In addition, the complaint form will be revised to replace ''Site Employee'' with ''Employee'' under the question ''What is your affiliation with the study?''

The comment asked whether the data collection is limited to good clinical practices (GCPs) and good laboratory practices (GLPs), and whether it pertains to current good manufacturing practices (CGMPs).

The comment recommended adding a check box so the complaint can be appropriately triaged to the correct office (e.g., that handles GCPs, GLPs, or CGMPs) within the appropriate Center.

(Response) It is anticipated that the complaints submitted to DSI will mostly pertain to GCPs and GLPs related to clinical studies involving FDA regulated drug products. The data collection is not intended to include CGMP issues. DSI will forward any complaints pertaining to CGMP issues to the appropriate divisions within FDA. Hence, the addition of a check box for CGMP does not offer any advantage and will not be added.

The comment suggested that FDA modify the question ''What is your complaint?'' to be more clear, and suggested that it be replaced with ''What information do you have that relates to questionable research or scientific misconduct with an FDA regulated product (biologic, device, drug, food, etc.).''

(Response) The question on the complaint form ''What is your complaint?'' is the most direct approach to eliciting the required information from a complainant. Hence, no modification of the question is necessary.

The comment recommended revising two existing questions to: ''What was the approximate timeframe related to the event to which you are reporting?''

(Response) The pertinent questions currently on the complaint form ''When did the event(s) take place?'' and ''When did you participate in the study?'' are the most direct approach to eliciting the required information from a complainant. Hence, no modification of these questions is necessary.

The comment suggested the insertion of a series of checkboxes, similar to the person or organization about which they are complaining, to indicate the type of regulated product. The comment stated that this will facilitate a quick triage to the appropriate center within FDA.

(Response) The form is for collecting complaints regarding FDA regulated drug products and is intended to be an adjunct to DSI's existing methods of collecting complaints. We do not anticipate receiving complaints about other FDA regulated products and hence do not need to insert additional checkboxes. If DSI receives complaints that pertain to other FDA regulated products, they will be forwarded to the appropriate center within FDA. The addition of check boxes is not likely to enhance or expedite this process.

The comment suggested using the question ''What is the name(s) of the medical products related to your report?'' to prompt the entry of brand name, trade name, generic name, and so forth.

(Response) The comment pertains to the complaint form question ''What is/are the name(s) of the study drug(s) or product(s), if known?'' The question currently on the complaint form is the most direct approach for eliciting the required information from a complainant. Modifying the question as suggested may unnecessarily confuse the complainant.

The comment suggested using the question ''What is the indication or intended use for the product?'' to query the intended use of the product. The comment noted that not all medical products are used to treat illness.

(Response) The comment pertains to the complaint form question ''What is the type of drug or for what illness is it used (e.g., a drug to treat chest pains, seizures, depression, etc.)?'' The question currently on the complaint form is the most direct approach to eliciting the required information from a complainant. The general population will not readily understand the use of words such as ''indication'' and ''intended use.''

The comment recommended that the complaint form be reformatted to use separate entry screens for e-mail, phone, fax, and so forth.

(Response) The comment pertains to the section of the complaint form entitled ''Your information.'' FDA agrees with the comment and will modify this section to include separate entry screens for e-mail, phone, and fax numbers. In addition, FDA will modify the same section to include separate entry screens for recording address(es), city, state or province, zip code, and country.

The comment suggested that the form should spell out such terms as ''Institutional Review Board'' and ''Contract Research Organization,'' and should also include ''clinical investigator.''

(Response) A radio button will be added for ''clinical investigator,'' and all abbreviations will be spelled out in the complaint form and as suggested by the comment.

(Comment 3) Another comment suggested that FDA use one research complaint form that would cover all FDA-regulated products. An example would be the MEDWATCH form. This would be much simpler for the public to use rather than each center within FDA creating their own form and related process. Additionally, it would bring research complaints associated with all FDA regulated investigational products to the agency's attention, thus making it easier to track and subsequently measure outcomes.

(Response) The purpose of this form is to collect information about potential scientific or research misconduct, or questionable research practices, involving the use of a FDA regulated drug product. It is anticipated that complaints submitted to DSI will mostly pertain to GCPs and GLPs related to clinical studies involving FDA regulated drug products. The data collection is not intended to include complaints pertaining to all FDA regulated products. DSI will forward any complaints regarding other FDA regulated products that are not under DSI's purview to appropriate divisions within FDA. The development of a universal research complaint form that covers all major FDA regulated products may offer advantages as suggested in the comment but would require substantial staff to redirect complaints.

Dated: December 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–24102 Filed 12–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0150]

Animal Drugs, Feeds, and Related Products; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 15 new animal drug applications (NADAs) because the products are no longer manufactured or marketed. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove portions reflecting approval of the NADAs.

DATES: Withdrawal of approval is effective December 27, 2005.

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9067, e-mail: *pesposit@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the 15 NADAs listed in table 1 of this document because the products are no longer manufactured or marketed:

TABLE 1.

Sponsor	NADA Number, Product (Drug)	21 CFR Section Affected (Sponsor Drug Labeler Code)
Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333–2435	NADA 119–063, Pyrantel Tartrate Ton Pack (pyrantel tartrate)	558.485 (051359)
Farmland Industries, Inc., Kansas City, MO 64116	NADA 138–656, BN Wormer—19.2 BANMINTH Premix (pyrantel tartrate)	558.485 (021676)
I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137	NADA 129–395, HYGROMIX 0.6 Premix (hygromycin B) NADA 129–646, TYLAN 10 Sulfa-G (tylosin, sulfamethazine) NADA 136–601, Swine Guard-BN (pyrantel tartrate)	558.274 (050639) 558.630 (050639) 558.485 (050639)
J. & R. Specialty Supply Co., 310 Second Ave., SW,, P.O. Box 506, Waseca, MN 56093	NADA 96–780, TYLAN 10; TYLAN 40 (tylosin)	n/a (049768)
Kerber Milling Co., Box 152, 1817 E. Main St., Emmetsburg, IA 50536	NADA 98–687, Hy-Test Hy-Boost TY 5 Medicated (tylosin)	558.625 (029341)
M & M Livestock Products Co., Eagle Grove, IA 50533	NADA 96–837, M & M Tylosin Premix (tylosin)	558.625 (026282)
Nutra-Blend Corp., P.O. Box 485, Neosho, MO 64850	NADA 129–161, Nutra-Blend TYLAN 10 Sulfa Premix (tylosin, sulfamethazine) NADA 136–384, Swine Wormer-BN BANMINTH (pyrantel tartrate)	558.630 (050568) 558.485 (050568)
South St. Paul Feeds, Inc., 500 Farwell Ave., South St. Paul, MN 55075	NADA 136–369, Custom Ban Wormer 9.6 (pyrantel tartrate)	558.485 (001800)
Stockton Hay & Grain Co.	NADA 49–462, Rainbrook Broiler Premix No. 1 (ampolium, arsanilic acid, ethopabate, penicillin G procaine, streptomycin) NADA 91–646, Rainbow Broiler Base Concentrate (ampolium, bacitracin zinc, ethopabate) NADA 91–647, Broiler Base Concentrate (ampolium, chlortetracyline, ethopabate)	n/a (036541) n/a (036541) n/a (036541)
Triple ''F'', Inc., 10104 Douglas Ave., Des Moines, IA 50322	NADA 131–146, FLAVOMYCIN 0.4 (bambermycins)	558.95 (011490)

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), 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 NADAs 49–462, 91–646, 91–647, 96–780, 96–837, 98–687, 119–063, 129–161, 129–395, 129–646, 131–146, 136–369, 136–384, 136–601, 138–656, and all supplements and