responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

Topics to be discussed at the meeting include vaccine safety recommendations, the National Vaccine Plan, adult immunization recommendations, vaccine financing, 2009 H1N1 influenza outbreak, and other related issues. The meeting agenda will be posted on the website: *www.hhs.gov/nvpo/nvac* at least one week prior to the meeting. Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the office at the address/phone listed above at least one week prior to the meeting. Members of the public will have the opportunity to provide comments at the meeting. Public comment will be limited to five minutes per speaker. Individuals who would like to submit written statements should e-mail or fax their comments to the National Vaccine Program Office at least five business days prior to the meeting. Those wishing to register may do so by sending an email to *nvpo@hhs.gov* or by calling 202–690–5566 and providing name, e-mail address and organization.

Dated: December 23, 2009.

Bruce Gellin,

Deputy Assistant Secretary for Health, Director, National Vaccine Program Office.

[FR Doc. E9–30897 Filed 12–29–09; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0546]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pet Food Early Warning Recall Rational Questionnaire as Part of the MedWatch^{Plus} Portal and Rational Questionnaire Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow for public comment in response to the notice. This notice solicits comments on the data elements for the Rational Questionnaire which is being rolled out as part of the ongoing MedWatch^{Plus} Portal and Rational Questionnaire initiative.

DATES: Submit written or electronic comments on the collection of information by January 29, 2010.

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

I. Background

Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

II. Pet Food Early Warning Recall Rational Questionnaire as Part of the MedWatch^{Plus} Portal and Rational Questionnaire Initiative (OMB Control No. 0910–0645)—Revision

Section 1002(b) of the FDA Amendments Act of 2007 (FDAAA) (Public Law 110–85), directs the Secretary of Health and Human Services (the Secretary), to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. As part of the effort to fulfill that directive, the Secretary tasked FDA with developing the instrument that would allow consumers to report voluntarily adverse events associated with pet food. In a 60-day **Federal Register** notice, which published on October 23, 2008 (73 FR 63153 at 63155), and a 30-day notice, which published on May 20, 2009 (74 FR 23721 at 23726), FDA announced the agency-wide information collection initiatives MedWatch^{Plus} Portal and Rational Questionnaire. These initiatives are components of a larger electronic system being developed to collect, submit, and process adverse event reports and other safety information for all FDA-regulated products. The MedWatch^{Plus} Portal, a Web-based portal, and the Rational Questionnaire, a user-friendly data collection tool, together make it easy for the public to report a safety problem.

In this 30-day notice, FDA is requesting public comment on data elements associated with the roll out of the Pet Food Early Warning System component of the overall MedWatch^{Plus}Portal and Rational Questionnaire initiative, whose framework and burden hours were approved under OMB Control Number 0910–0645. This notice refers to the instrument described in that information collection. FDA previously estimated the total burden hours associated with the Pet Food Early Warning System to be 324 hours (73 FR 63153 at 63155; 74 FR 23721 at 23726). The estimated burden hours associated with this information collection remain 324 total hours.

III. Data Elements for Pet Food Early Warning System Rational Questionnaire

In this 30-day notice, FDA is requesting public comment on data elements associated with the Pet Food Early Warning System component of the MedWatch^{Plus} Portal and Rational Questionnaire initiatives. Following is a

table describing the data elements to be included in the instrument.

TABLE 1.—DATA ELEMENTS FOR VOLUNTARY PET FOOD REPORTS OF PRODUCT PROBLEMS AND/OR ADVERSE EVENTS SUBMITTED THROUGH THE MEDWATCH^{PLUS} RATIONAL QUESTIONNAIRE SAFETY REPORTING PORTAL

Data Element	Description
Introduction Page	
Report Identifying Information	
*Which of the following best describes you?	This describes whether the reporter is a consumer/private citizen, or a veterinary professional.
*Enter a name to help you identify the report.	This requests that the reporter enter a short name, description, or title that the reporter associates with the event reported.
*What type of report are you submitting?	This describes the type of report being submitted (e.g., adverse event, product problem, or both).
*Are you the animal owner?	This indicates whether the reporter is the owner of an animal involved in the report.
Contact Information Page	
Your Contact Information	
First Name	This is the reporter's first name.
Last Name	This is the reporter's last name.
*May the FDA contact you to follow-up, if necessary?	This indicates whether FDA may contact the reporter if follow-up information is needed.
E-mail	This is the reporter's e-mail address.
Confirm e-mail	This requests that e-mail information be confirmed by the reporter.
Primary Phone	This is the reporter's primary phone number.
Other Phone	This is the reporter's alternate phone number.
Country	This is the reporter's country of residence.
Street Address Line 1	This is the street address of the reporters primary residence.
Street Address Line 2	This is additional street address information for the reporter's primary residence (if additional lines are necessary to report that information).
City/Town	This is the reporter's city or town of residence.
State	This is the reporter's State of residence.
ZIP/Postal Code	This is the zip code for the reporter's residence.
Other Parties Reported To	
Indicate any other parties that you notified about this issue	This asks the reporter to identify (in general) other parties told about the problem being reported to FDA.
Problem Summary Page	
Affected Animal Information	
Number of animals given the product	This asks about the number of animals that received the product.
*Number of animals reacted	This asks about the number of animals that became ill or had a reaction after receiving the product.
Animal Name/Identifier	This asks the reporter to provide a name or other means to identify the animal(s) involved in the report.
*Species	This is a list of values describing the species of the animal(s) involved in the report.

TABLE 1.—DATA ELEMENTS FOR VOLUNTARY PET FOOD REPORTS OF PRODUCT PROBLEMS AND/OR ADVERSE EVENTS SUBMITTED THROUGH THE MEDWATCH^{PLUS} RATIONAL QUESTIONNAIRE SAFETY REPORTING PORTAL—Continued

Data Element	Description
*Breed	This is a list of values describing the breed(s) of the animal(s) involved in the report.
Age	This is the animal's age.
Weight	This is the animal's weight.
Gender	This asks the reporter to identify the gender (sex) of the animal involved in the report.
*Reproductive status	This asks the reporter to identify whether the animal's reproductive organs are intact or whether the animal had been neutered (e.g., sterilized, castrated or spayed).
*Was animal pregnant at time of event?	This asks the reporter to identify whether the animal was pregnant at the time of the adverse event.
*Was the animal lactating at time of event?	This asks the reporter to identify whether the animal was producing milk at the time of the adverse event.
Prior to the event what was the animal's overall state of health?	This asks the reporter to identify the overall or general state of the animal's health before the adverse event.
Medical History	
Did the animal have any health problems and/or was the animal taking medication prior to the event?	This asks the reporter to identify whether the animal was taking medication or had a health problem before the adverse event.
Problem Description	
*Describe what happened	This asks the reporter to describe in a narrative what was observed with the product, and/or how the animal reacted to the product.
*Date problem started	This asks the reporter what date the problem started.
Date of recovery	This is the date the animal recovered from the illness associated with, or the reaction to, the product.
*Outcome to date	This requests that the reporter identify the current condition of the animal.
*Date of death	This is the date the animal died (if applicable).
Products Page	
Product Details	
*Product Brand Name	This is the name of the product.
UPC from Label	This is the 12-digit bar code that can be found on the product label.
*Product Type	This asks the reporter to identify whether the product is food for people, food for pet animals, or food for other animals, such as livestock, zoo, or research animals.
Was product recalled?	This asks the reporter to identify whether the reporter knows if the manufacturer has removed from sale and destroyed the product being reported, regardless of whether the manufacturer did so voluntarily or at the request of a government agency.
Package Type	This is a list of values for the type of package or container for the product.
Package Size	This asks the reporter to provide information on the quantity of the product contained in the package.
Date last purchased product	This is the date the product was last purchased.
Number purchased on this date	This asks the reporter to enter the number of packages, containers, or other units of the product purchased on the date the product was last purchased.

TABLE 1.—DATA ELEMENTS FOR VOLUNTARY PET FOOD REPORTS OF PRODUCT PROBLEMS AND/OR ADVERSE EVENTS SUBMITTED THROUGH THE MEDWATCH[PLUS] RATIONAL QUESTIONNAIRE SAFETY REPORTING PORTAL—Continued

Data Element	Description
If the product is reconstituted, what is the percentage of the product that is water?	This asks the reporter to provide information for the proportion (expressed as a percentage) of the final product fed that is water, if water is added to the product before feeding it.
Were there any other foods or products given to the animal during this period of time?	This asks the reporter to identify whether the animal was fed any other foods or supplements during the time the animal was fed the product.
Do you have a package/container of unopened product from this purchase?	This asks the reporter to identify whether the reporter has any remaining unopened packages or containers of the product.
Describe how the product was stored before and after opening.	This asks the reporter to describe how the product was stored in the user's home before it was opened and after it was opened.
Product Use Details	
Describe how the product was used or administered.	This asks the reporter to describe how the product was given to the animal.
Date first fed the animal product from this purchase	This is the first date the animal received product from the most recent purchase of that product.
Date last fed the animal product from this purchase	This is the last date the animal received product from the most recent purchase of that product.
Percentage of daily ration of product that animal consumed.	This asks the reporter to provide an estimate of the percentage of the animal's total diet that is represented by the product being reported.
How Product Was Used	
Amount of time from use of product to onset of the event?	This asks the reporter to provide information on the amount of time the product was used before the animal became ill or reacted to the product.
Was the product use stopped after the onset of the adverse event?	This asks the reporter to identify whether the use of the product was stopped after the animal became ill or reacted to the product.
Did the adverse event diminish or stop after the product use was stopped?	This asks the reporter to identify whether the signs of illness or reaction stopped or lessened after use of the product was stopped.
Was product use started again?	This asks the reporter to indicate whether the product was used again after its use was stopped.
Length of waiting period between stopping and restarting product use	This is the amount of time between stopping use of the product and restarting the use of the product (if applicable).
Did the adverse event reappear after reintroducing this product?	This requests the reporter identify whether the illness or reaction to the product occurred again after the use of the product was restarted (if applicable).
In your opinion, how likely is it that the use of this product is related to the adverse event?	This requests the reporter to indicate how strongly the reporter believes the use of the product caused the illness or adverse reaction.
Product Purchase Location	
Store/place of purchase.	This is the name of the store or the Web address from which the product was purchased.
Country	This is the country associated with the store or the Web address from which the product was purchased.
Street Address Line 1	This is the street address associated with the store or the Web address from which the product was purchased.
Street Address Line 2	This is additional street address information associated with the store or the Web address from which the product was purchased (if additional lines are necessary to report that information).

TABLE 1.—DATA ELEMENTS FOR VOLUNTARY PET FOOD REPORTS OF PRODUCT PROBLEMS AND/OR ADVERSE EVENTS SUBMITTED THROUGH THE MEDWATCH[PLUS] RATIONAL QUESTIONNAIRE SAFETY REPORTING PORTAL—Continued

Data Element	Description
City/Town	This is the city or town associated with the store or the Web address from which the product was purchased.
State	This is the State associated with the store or the Web address from which the product was purchased.
State/Province	This is the State/Province associated with the store or the Web address from which the product was purchased.
ZIP/Postal Code	This is the zip code associated with the store or the Web address from which the product was purchased.
Firm/Organization on Label	
Do you have one or more labels from this product?	This requests the reporter to indicate whether the reporter has one or more labels from the product being reported.
Firm/Organization Name	This is name of the firm that appears on the label.
Firm/Organization Type	This is the type of firm whose name appears on the label.
Country	This is the country associated with the firm that appears on the label.
Primary Phone	This is the primary phone number associated with the firm that appears on the label.
Street Address Line 1	This is the street address associated with the firm that appears on the label.
Street Address Line 2	This is additional street address information associated with the firm that appears on the label (if additional lines are needed to report that information).
City/Town	This is the city or town associated with the firm that appears on the label.
State	This is the State associated with the firm that appears on the label.
State/Province	This is the State/Province associated with the firm that appears on the label.
ZIP/Postal Code	This is the zip code associated with the firm that appears on the label.
Web address	This is the Web address for the firm whose name appears on the label.
Product Lots	
Lot Number	This requests the reporter to provide the lot number or production code that can be found on the label.
Expiration/use-by date	This is the month and year of an expiration date or use-by (best-by, best-before) date that appears on the label.
Veterinarian Visits Page	
Veterinary Visit Details	
Was a veterinarian consulted?	This requests the reporter to indicate whether a veterinarian was consulted about the illness or reaction the animal had to the product.
Veterinarian Information	
*First Name	This is the first name of the veterinarian who was consulted.
*Last Name	This is the last name of the veterinarian who was consulted.
Veterinary Practice Name	This is the name of the veterinary practice in which the veterinarian that was consulted works.

TABLE 1.—DATA ELEMENTS FOR VOLUNTARY PET FOOD REPORTS OF PRODUCT PROBLEMS AND/OR ADVERSE EVENTS SUBMITTED THROUGH THE MEDWATCH[PLUS] RATIONAL QUESTIONNAIRE SAFETY REPORTING PORTAL—Continued

Data Element	Description
Country	This is the country of the veterinary practice where the animal was examined.
Street Address Line 1	This is the street address of the veterinary practice where the animal was examined.
Street Address Line 2	This is additional street address information for the veterinary practice where the animal was examined (if additional lines are needed to report that information).
City/Town	This is the city or town of the veterinary practice where the animal was examined.
State	This is the State of the veterinary practice where the animal was examined.
ZIP/Postal Code	This is the zip code of the veterinary practice where the animal was examined.
E-mail	This is the e-mail address of the veterinary practice where the animal was examined.
*Primary Phone	This is the primary phone number of the veterinary practice where the animal was examined.
Attachments Page	
Attach File	
*Description of Attachment	This requests the reporter provide a brief description of the file being attached, e.g., scanned label or medical records.
*Type of Attachment	This requests the reporter indicate the specific contents of the attachment.
* Indicates the information or a response is necessary for FDA to fully process a report.	

IV. Request for Comments

FDA invites comments on all aspects of the collection of the data elements for this Pet Food Early Warning System Rational Questionnaire. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the proposed changes. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 22, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–30872 Filed 12–29–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

List of Recipients of Indian Health Scholarships Under the Indian Health Scholarship Program

The regulations governing Indian Health Care Improvement Act Programs (Pub. L. 94–437) provide at 42 CFR 136.334 that the Indian Health Service shall publish annually in the **Federal Register** a list of recipients of Indian Health Scholarships, including the name of each recipient, school and Tribal affiliation, if applicable. These scholarships were awarded under the authority of Sections 103 and 104 of the Indian Health Care Improvement Act, 25 U.S.C. 1613–1613a, as amended by the Indian Health Care Amendments of 1988, Public Law 100–713.

The following is a list of Indian Health Scholarship Recipients funded under Sections 103 and 104 for Fiscal Year 2009:

Ahpeahtone, Edwin Paul, University of Oklahoma, Delaware Nation, Oklahoma.

Alexander, Laura Lee, Pennsylvania College of Optometry, Native Village of Selawik, Alaska.

Amdur-Clark, Micah Evan, Northeastern University, Citizen Potawatomi Nation, Oklahoma.

Anagale, Paul Todd, University of Minnesota/Duluth, Navajo Nation, Arizona, New Mexico & Utah.

Anderson, Debra Jean, Northern Arizona University, White Earth Band of the Minnesota Chippewa Tribe, Minnesota.

Avery, Shaela Ann, University of Utah College of Medicine, Navajo Nation, Arizona, New Mexico & Utah.

Azure, Joan Marie, Dakota State College, Turtle Mountain Band of Chippewa Indians of North Dakota.

Azure, Krysten Ross, University of North Dakota, Turtle Mountain Band of Chippewa Indians of North Dakota.

Bacon, Kyle, Idaho State University College of Pharmacy, Shoshone Tribe of the Wind River Reservation, Wyoming.