Comment Due Date: Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: November 6, 2009.

Yvette Roubideaux,

Director, Indian Health Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0556]

Agency Information Collection Activities; Proposed Collection; Comment Request; Records and Reports Concerning Experience With Approved New Animal Drugs; Proposed New Data Elements for Adverse Event Reports on Revised Forms FDA 1932 and 1932a

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 requirements for recordkeeping and reports concerning experience with approved new animal drugs, specifically on new data elements to be used in revised versions of Forms FDA 1932 and 1932a. The information contained in the reports required by this regulation enables FDA to monitor the use of new animal drugs after approval and to ensure their continued safety and efficacy.

DATES: Submit written or electronic comments on the collection of information by December 21, 2009.

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, Office of Management Programs (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. Records and Reports Concerning Experience With Approved New Animal Drugs; Proposed New Data Elements for Adverse Event Reports on Revised Forms FDA 1932 and 1932a; 21 CFR 514.80 (OMB Control No. 0910–0645)—Revision

Section 512(l) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360b(l)) and § 514.80(b) of FDA regulations (21 CFR 514.80) require applicants of approved new animal drug applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects.

This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Postapproval marketing surveillance is important because data previously submitted to FDA may no longer be adequate, as animal drug effects can change over time and less apparent effects may take years to manifest.

An applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs'' (see § 514.80(d)). Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report,'' allows for voluntary reporting of adverse drug experiences or product/manufacturing defects.

Collection of information using existing paper forms FDA 2301, 1932, and 1932a is currently approved under OMB control number 0910–0284, set to expire on January 31, 2010. FDA currently is seeking renewal of that information collection.

FDA recently proposed to collect information using electronic versions of Forms FDA 1932 and 1932a as part of the agency-wide information collection (MedWatch^{Plus} Portal and Rational Questionnaire) that was announced for public comment in the **Federal Register** on October 23, 2008 (73 FR 63153). The MedWatch^{Plus} Portal and Rational Questionnaire are components of a new electronic system for collecting, submitting, and processing adverse event reports and other safety information for all FDA-regulated products.

In this 30-day notice, FDA is requesting public comment on data elements associated with revisions to forms FDA 1932 and 1932a (both paper and electronic) under revised OMB control number 0910–0645, described below. We will publish separately in the **Federal Register** a 30-day notice to complete the renewal of OMB control number 0910–0284, the collection of information using existing paper forms FDA 2301, 1932, and 1932a, to provide time for development of the revised FDA Forms 1932 and 1932a and their incorporation into the MedWatch OMB

control number 0910–0645. After these forms have been incorporated under MedWatch OMB control number 0910–0645, they will cease to exist under OMB control number 0910–0284. FDA Form 2301 will continue without revision under OMB control number 0910–0284.

This 30-day notice lists the data elements associated with revised versions of both paper and electronic forms 1932 and 1932a under a revision to OMB control number 0910–0645. It is estimated that, during the first 3 years that the MedWatch^{Plus} Portal is in use, half of the reports will be submitted in paper format and half will be submitted electronically.

The reporting and recordkeeping burden estimates, including the total number of annual responses, are based on the submission of reports to the Division of Surveillance, Center for Veterinary Medicine. The hours per response for both paper and electronic versions of revised Forms FDA 1932 and 1932a are assumed to be the time it will take to gather the required information and complete each form. The annual frequency of responses was calculated as the total annual responses divided by the number of respondents.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section or Section of the Act	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3); Paper Version	1932[2]	404	44.264	17,882.5	1.5	26,824
514.80(b)(1), (b)(2)(i), (b)(2)(ii), and (b)(3); Electronic Version	1932[2],	404	44.264	17,882.5	1	17,882.5
Voluntary reporting FDA Form 1932a for public; Paper Version	1932a[3]	81.5	1	81.5	1	81.5
Voluntary reporting FDA Form 1932a for public; Electronic Version	1932a[3]	81.5	1	81.5	0.6	48.9
Total Hours						44,836.9

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

[2] FDA received 35,765 mandatory reports (Form FDA 1932) during 2007 from 808 respondents. Based on this experience, and taking into account the data element revisions, we estimate that CVM will receive 35,765 mandatory reports from 808 respondents annually. We estimate that one half of the respondents (404) will use the paper form, while the other half (404) will submit electronically; that is, we will receive 17,882.5 reports in paper form, and 17,882.5 reports electronically. We estimate the reporting burden for mandatory reporting to be: Paper form: 26,824 hours (404 respondents x 44.264 annual frequency of response x 1.5 hours ≈ 26,824 hours). Electronic form: 17,882.5 hours (404 respondents x 44.264 annual frequency of response x 1 hour ≈ 17,882.5 hours).

[3] FDA received 163 voluntary reports (Form FDA 1932a) during 2007. Based on this experience, and taking into account the data element revisions, we estimate that CVM will receive 163 voluntary reports from 163 respondents annually. We estimate that one half of the respondents (81.5) will use the paper form, while the other half (81.5) will submit electronically; that is, we will receive 81.5 reports in paper form, and 81.5 reports electronically. We estimate the reporting burden for voluntary reporting to be: Paper form: 81.5 hours (81.5 respondents x 1 annual frequency of response x 1 hour per report = 81.5 hours). Electronic form: 48.9 hours (81.5 respondents x 1 annual frequency of response x 0.6 hours per report = 48.9 hours).

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
514.80(e)[2]	90	55	4,949	0.5	2,475[3]

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

[2] Section 514.80(e) covers recordkeeping hours for adverse event reporting on revised forms 1932 and 1932a.

[3] The annual frequency of responses was calculated as the total annual responses divided by the number of respondents.

III. Revisions to Forms FDA 1932 and 1932a and Request for Comments

A. Background on Revisions

Section 514.80(d) of FDA's regulations requires applicants of approved NADAs and ANADAs to report adverse drug experiences and product and manufacturing defects associated with their new animal drug products using Form FDA 1932. For voluntary reporting, Form FDA 1932a should be used instead.

As part of FDA's ongoing effort to harmonize the agency's adverse event (AE) regulatory reporting requirements with those of other nations and streamline reporting for product and manufacturing defects, FDA is contemplating changes to the data elements reported on Forms FDA 1932 and 1932a. Furthermore, the contemplated changes to Forms FDA 1932 and 1932a are based on FDA's experience in determining the safety and effectiveness of product(s) and need for efficient data capture and entry.

The contemplated changes to the AE reporting requirements for Form FDA 1932 are the product of discussions undertaken between the United States, Japan, and the European Union as part of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). FDA is considering revisions to Form FDA 1932 that would bring the AE reporting data elements on the form more in line with the data elements developed as a result of the VICH discussions.[1] The agency also is

[1] FDA will implement all of the VICH data elements verbatim from the draft guidance document entitled ''Pharmacovigilance of Veterinary Medicinal Products Data Elements for Submission of Adverse Event Reports'' (VICH GL–42), in Form FDA 1932. VICH GL–42 is currently

contemplating the inclusion of additional new data elements that would gather information specific only to FDA. Collecting this FDA-specific information is essential for the processing, review, and regulatory disposition of the electronic and paper reports. Inclusion of some of the new data elements is necessitated by the Rational Questionnaire.

In addition, the agency is considering adding new data elements for product and manufacturing defect reports on Form FDA 1932 and 1932a. These changes are the product of internal FDA discussions and are intended to capture additional pertinent product and manufacturing defect information.

B. Proposed Revisions

1. Form FDA 1932

This section describes data elements on the current Form FDA 1932, proposed new data elements, and data elements we propose to delete from the current form. These AE and product and manufacturing defect data elements will be collected electronically, through the MedWatch^{Plus} Portal and Rational Questionnaire (currently under development), and in the paper form.

Table 3 of this document, entitled ''Data Elements for Form FDA 1932,'' presents the data elements for the collection of animal drug adverse event reports and manufacturing and product defect reports. The data elements are listed in the column entitled ''Data Elements.'' The column entitled ''Current, New, or Deleted Data Element'' indicates whether the data element is currently being collected (Current)[2], is a proposed new data element (New), or is a data element FDA proposes to delete (Deleted).

As previously mentioned in this document, the agency has had discussions with VICH regarding the data elements to be collected for animal drug adverse events. As a result, the agency is proposing new data elements that have been negotiated with VICH. The column entitled ''VICH-Negotiated or FDA-Proposed Data Element'' differentiates between VICH-negotiated and FDA-proposed data elements.

The agency intends to allow the regulated industry to submit this information collection in three different submission/transmission formats. Industry will be able to submit these reports using a paper form, the Web-based Rational Questionnaire, or an electronic file through the FDA electronic Gateway-to-Gateway transmission. The column entitled ''Submission/Transmission Format'' presents the submission/transmission format(s) that will be used with each particular data element.

TABLE 3.—DATA ELEMENTS FOR FORM FDA 1932

Line No.	Data Elements	Current, New, or Deleted Data Element	VICH-Negotiated or FDA-Proposed Data Element	Submission/Transmission Format (Paper Form, Electronic Web-based Rational Questionnaire (EWBRQ), and/or Electronic Gateway-to-Gateway (EGG))
1	United States-Only Specific Information, including:			
2	Report Identifier (The Report Identifier is the FDA application or file number of the AER being sent.)	Current	FDA Proposed	All Formats
3	Domestic vs. Foreign Category (This is a list of values describing whether the product is an FDA-approved product, a foreign-approved product, or other type of product, e.g., an unapproved drug.)	New	FDA Proposed	All Formats
4	United States Pharmacovigilance Contact Person for the Applicant or Nonapplicant (This is the person within the United States acting on behalf of the applicant or nonapplicant and is the contact person for the FDA for any pharmacovigilance issues about the report.), including:			
5	Title, First and Last Name	Current	FDA Proposed	All Formats
6	Telephone Number, Fax Number, and E-Mail Address	New	FDA Proposed	All Formats
7	Message Sender Identifier (Name and contact information of person responsible for any corresponding communications regarding the whole batch electronic transmission.), including:			
8	Street Address, City, State/County, and Mail/Zip Code	New	FDA Proposed	EGG Only
9	Three-character Country Code (This is the list of country codes from the International Organization for Standardization (ISO) 3166 standard.)	New	FDA Proposed	EGG Only
10	First and Last Name	New	FDA Proposed	EGG Only
11	Telephone Number, Fax Number, and E-Mail Address	New	FDA Proposed	EGG Only
12	Profile Identifier Code (This information indicates the type of report contained in the electronic message.)	New	FDA Proposed	EWBRQ and EGG Only

under discussion at Step 6. This guidance is available on the Internet at *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm.*

[2] In general, the information being collected is the same, but the data element has been renamed or restructured to facilitate data collection.

TABLE 3.—DATA ELEMENTS FOR FORM FDA 1932—Continued

Line No.	Data Elements	Current, New, or Deleted Data Element	VICH-Negotiated or FDA-Proposed Data Element	Submission/Transmission Format (Paper Form, Electronic Web-based Rational Questionnaire (EWBRQ), and/or Electronic Gateway-to-Gateway (EGG))
13	Batch ID (This information identifies the reports in this batch as a whole electronic message.)	New	FDA Proposed	EGG Only
14	Message Date (This information indicates the date this batch report is created.)	New	FDA Proposed	EGG Only
15	Message Version Number & Release Number (This information indicates the Health Level Seven, Inc. (HL7) ''Message Version'' and ''Release Number'' on which this batch report electronic submission is based.)	New	FDA Proposed	EGG Only
16	Adverse Event Report (AER) Information, including:			
17	Unique AER Identification Number (This globally unique AER identification number is created by and assigned by the applicant or nonapplicant.)	New	VICH Negotiated	All Formats
18	Original Receive Date (The original receive date is the date on which the first full communication of the AER was received by the applicant or nonapplicant responsible for reporting the AER to the FDA.)	Current	VICH Negotiated	All Formats
19	Date of Current Submission (This is the date the current AER was submitted to the Regulatory Authority (RA).)	Current	VICH Negotiated	All Formats
20	Type of Report, including:			
21	Type of Submission (This is a list of values describing the regulatory type of report being submitted to the RA, e.g., 15-day NADA/ANADA alert report, 3-day NADA/ANADA field alert report, followup report, nullification report, periodic drug experience report, and other report.)	Current	VICH Negotiated	All Formats
22	Reason for Nullification Report (This is a text description of why this AER is being nullified.)	Current	VICH Negotiated	All Formats
23	Type of Information in Report (This is a list of values for the categorization of the type of information in the AER, e.g., spontaneous safety and lack of expected effectiveness information, clinical study safety information, product and manufacturing defect information, product and manufacturing defect with safety and lack of expected effectiveness information, and other type of information.)	New	VICH Negotiated	All Formats
24	Regulatory Authority (RA) Information (This is the RA to which this AE report (AER) is to be initially submitted based on the RA that has authority to regulate the product.), including:			
25	RA Name	Current	VICH Negotiated	All Formats
26	Street Address, City, State/County, and Mail/Zip Code	Current	VICH Negotiated	All Formats
27	Three-character Country Code	Current	VICH Negotiated	All Formats
28	Marketing Authorization Holder (MAH) information. (The MAH is the applicant or the nonapplicant who is responsible for reporting the AER to the RA.), including:			
29	Business Name	Current	VICH Negotiated	All Formats
30	Street Address, City, State/County, and Mail/Zip Code	Current	VICH Negotiated	All Formats
31	Three-character Country Code	Current	VICH Negotiated	All Formats
32	Person Acting on Behalf of the MAH information, including:			
33	Title, First and Last Name	Current	VICH Negotiated	All Formats

TABLE 3.—DATA ELEMENTS FOR FORM FDA 1932—Continued

Line No.	Data Elements	Current, New, or Deleted Data Element	VICH-Negotiated or FDA-Proposed Data Element	Submission/Transmission Format (Paper Form, Electronic Web-based Rational Questionnaire (EWBRQ), and/or Electronic Gateway-to-Gateway (EGG))
34	Telephone Number, Fax Number, and E-Mail Address	New	VICH Negotiated	All Formats
35	Primary Reporter's information (The primary reporter is the person or organization, as determined by the MAH, which holds or provides the most pertinent information related to this AER.), including:			
36	First and Last Name	Current	VICH Negotiated	All Formats
37	Telephone and Fax Number	Current	VICH Negotiated	All Formats
38	E-Mail Address	New	VICH Negotiated	All Formats
39	Business Name	Current	VICH Negotiated	All Formats
40	Street Address, City, State/County, and Mail/Zip Code	Current	VICH Negotiated	All Formats
41	Three-character Country Code	Current	VICH Negotiated	All Formats
42	Primary Reporter Category (This is a list of values describing the role/involvement of the primary reporter, e.g., animal owner, physician, et cetera.)	New	VICH Negotiated	All Formats
43	Other Reporter's information (The other reporter is the person or organization, determined by the MAH, who also possesses pertinent information related to this AER.), including:			
44	First and Last Name	Current	VICH Negotiated	All Formats
45	Telephone and Fax Number	Current	VICH Negotiated	All Formats
46	E-Mail Address	New	VICH Negotiated	All Formats
47	Business Name	Current	VICH Negotiated	All Formats
48	Street Address, City, State/County, and Mail/Zip Code	Current	VICH Negotiated	All Formats
49	Three-character Country Code	Current	VICH Negotiated	All Formats
50	Other Reporter Category (This is a list of values describing the role/involvement of the other reporter, e.g., animal owner, physician, et cetera.)	New	VICH Negotiated	All Formats
51	Veterinary Medical Product (VMP) and Data Usage (for all VMPs), including:			
52	Registered or Brand Name (This is the name by which the product is presented by the MAH, also known as the Proprietary Name or Trade Name of the product.)	Current	VICH Negotiated	All Formats
53	Product Code (The product code is the National Drug Code (NDC) number for U.S. FDA-regulated products.)	New	VICH Negotiated	All Formats
54	Registration Identifier (The Registration Identifier is the code for where the VMP is approved, what RA is responsible for regulating VMP, and the registration number of the VMP.)		VICH Negotiated	All Formats
55	ATCvet Code (ATCvet stands for Anatomic Therapeutic Chemical System for Veterinary Medicine. It is used for the classification of substances intended for therapeutic use and can serve as a tool for the classification of veterinary medicinal products. More information about the ATCvet code is available at *http://www.whocc.no/atcvet/*)	New	VICH Negotiated	All Formats
56	Who Administered the VMP (This is a list of values describing the person who administered the VMP(s) to the animal involved in the AE, e.g., veterinarian, animal owner, et cetera.)	Current	VICH Negotiated	All Formats

TABLE 3.—DATA ELEMENTS FOR FORM FDA 1932—Continued

Line No.	Data Elements	Current, New, or Deleted Data Element	VICH-Negotiated or FDA-Proposed Data Element	Submission/Transmission Format (Paper Form, Electronic Web-based Rational Questionnaire (EWBRQ), and/or Electronic Gateway-to-Gateway (EGG))
57	Company or MAH (This is the name(s) of the company or MAH that owns the VMP(s) involved in the AE.)	Current	VICH Negotiated	All Formats
58	MAH Assessment (This is the assessment by the MAH of the association between the use of the VMP and the AE.)	Current	VICH Negotiated	All Formats
59	FDA, Office of Regulatory Affairs (ORA) District Field Office (This is a list of values identifying the ORA District Field Office or local FDA residence post to which the product and manufacturing defect information was submitted. This field is used for product and manufacturing defect reports and if the report is both an AE and a product and manufacturing defect report.)	New	FDA Proposed	All Formats
60	Use According to Label (This element requests information regarding whether the VMP(s) was used according to its label.)	Current	VICH Negotiated	All Formats
61	Explanation for Off-Label Use Code (This is the list of values describing how the VMP was used in an off-label (extralabel) manner.)	New	VICH Negotiated	All Formats
62	Active Ingredient information, including:			
63	Active Ingredient(s) (These are the names of the pharmaceutical substances that comprise the active component of the VMP.)	Current	VICH Negotiated	All Formats
64	Strength and Strength Unit (Numerator and Denominator) (Strength is the concentration of the active ingredient.)	Current	VICH Negotiated	All Formats
65	Active Ingredient Code (The active ingredient code is the Unique Ingredient Identifier (UNII) code. The UNII code is generated by the joint FDA/United States Pharmacopeia (USP) Substance Registration System (SRS).)	New	VICH Negotiated	All Formats
66	Dosage Form (This is a selection for a list of values for the labeled dosage form of the VMP(s).)	Current	VICH Negotiated	All Formats
67	Dosing Information, including:			
68	Date of First Exposure (Day, Month, Year) (This is the date on which the animal was first treated with the VMP.)	Current	VICH Negotiated	All Formats
69	Date of Last Exposure (Day, Month, Year) (This is the date on which the animal was last treated with the VMP.)	Current	VICH Negotiated	All Formats
70	Numeric Value and Unit for Interval of Administration (This is the frequency of administration of the VMP(s).)	Current	VICH Negotiated	All Formats
71	Numeric Value and Unit for Dose (This is the actual quantity of the dose administered.)	Current	VICH Negotiated	All Formats
72	Route of Exposure (This is a selection from a list of values for the route by which the VMP was administered.)	Current	VICH Negotiated	All Formats
73	Lot Number Information, including:			
74	Lot Number (This is the lot number associated with the VMP in this AER.)	Current	VICH Negotiated	All Formats
75	Expiration Date (Day, Month, Year) (This is the expiration date associated with the lot number.)	New	VICH Negotiated	All Formats
76	Manufacturing Site Identifier Number (This is the FDA Establishment Number (FEI Number) or the Data Universal Number System (D-U-N-S® Number.)	New	FDA Proposed	All Formats

TABLE 3.—DATA ELEMENTS FOR FORM FDA 1932—Continued

Line No.	Data Elements	Current, New, or Deleted Data Element	VICH-Negotiated or FDA-Proposed Data Element	Submission/Transmission Format (Paper Form, Electronic Web-based Rational Questionnaire (EWBRQ), and/or Electronic Gateway-to-Gateway (EGG))
77	Manufacturer's Identifier Type (This is a list of values describing the type of manufacturing site identifier number, i.e., FEI Number or D-U-N-S® Number.)	New	FDA Proposed	All Formats
78	Manufacturing Date (Day, Month, Year) (This is the date the VMP was manufactured.)	New	FDA Proposed	All Formats
79	Number of Defective Units (This is the number of defective units associated with this VMP.)	New	FDA Proposed	All Formats
80	Number of Units Returned (This is the number of defective units associated with this VMP returned to the applicant or non-applicant.)	New	FDA Proposed	All Formats
81	Adverse Event Information, including:			
82	Attending Veterinarian's Assessment (This is a list of values describing the assessment of the attending veterinarian regarding the association between the VMP(s) and the AE (other than human).)	Current	VICH Negotiated	All Formats
83	Previous Exposure to the VMP (Was the animal previously exposed to the VMP(s)?)	Current	VICH Negotiated	All Formats
84	Previous AE to the VMP (Did the animal have a previous AE to the VMP(s)?)	Current	VICH Negotiated	All Formats
85	Duration and Time Units (This is the length of time the AE lasted.)	Current	VICH Negotiated	All Formats
86	Serious AE (Was the AE serious?)	Current	VICH Negotiated	All Formats
87	Treatment of AE (Was the AE treated?)	Current	VICH Negotiated	All Formats
88	Outcome to Date, including: (number of)			
89	Recovered/Normal, Ongoing, Recovered with Sequela, and Unknown	Current	VICH Negotiated	All Formats
90	Euthanized	New	VICH Negotiated	All Formats
91	Died	Current	VICH Negotiated	All Formats
92	Length of Time Between Exposure to VMP(s) and Onset of AE (This is a list of values describing the length of time between the first exposure to the VMP and the onset of the AE.)	Current	VICH Negotiated	All Formats
93	Date of Onset of AE (Day, Month, Year) (This is the date of the first clinical manifestation of the AE.)	Current	VICH Negotiated	All Formats
94	Adverse Clinical Manifestations (This is a list of values describing the clinical signs that occurred during the AE.)	Current	VICH Negotiated	All Formats
95	Narrative of AE (open text field) (This is a detailed description of the case, regardless of the type of information contained in the report.)	Current	VICH Negotiated	All Formats
96	Did the AE Abate After Stopping the VMP?	Current	VICH Negotiated	All Formats
97	Did the AE Reappear After Re-Introduction of the VMP?	Current	VICH Negotiated	All Formats
98	Animal Data, including:			
99	Species (This is a list of values describing the species of the animal(s) involved in the AER.)	Current	VICH Negotiated	All Formats

TABLE 3.—DATA ELEMENTS FOR FORM FDA 1932—Continued

Line No.	Data Elements	Current, New, or Deleted Data Element	VICH-Negotiated or FDA-Proposed Data Element	Submission/Transmission Format (Paper Form, Electronic Web-based Rational Questionnaire (EWBRQ), and/or Electronic Gateway-to-Gateway (EGG))
100	Breeds and Crossbreed Information (This is a list of values describing the breed(s) of animal(s) involved in the AER.)	Current	VICH Negotiated	All Formats
101	Gender (This is a list of values for the selection of the gender(s) of animal(s) involved in the AER.)	Current	VICH Negotiated	All Formats
102	Reproductive Status (This is a list of values describing if the animal is intact, neutered, etc.)	Current	VICH Negotiated	All Formats
103	Female Physiological Status. (This is a list of values describing the animal's pregnancy and lactation status.)	Current	VICH Negotiated	All Formats
104	Age (Measured, Estimated, Unknown), including:			
105	Precision Value for Age (Measured, Estimated, Unknown Age. This is a list of values describing whether the age(s) provided are measured or estimated, or if age is not known.)	New	VICH Negotiated	All Formats
106	Minimum Age Value and Units.	Current	VICH Negotiated	All Formats
107	Maximum Age Value and Units.	Current	VICH Negotiated	All Formats
108	Weight, including:			
109	Precision Value for Weight (Measured, Estimated, Unknown Weights) (This is a list of values describing whether the weight(s) provided are measured or estimated, or if weight is not known.)	New	VICH Negotiated	All Formats
110	Minimum Weight	Current	VICH Negotiated	All Formats
111	Maximum Weight	Current	VICH Negotiated	All Formats
112	Attending Veterinarian's Assessment of Animal Health Status Prior to VMP. (This is a list of values describing the attending veterinarian's assessment of the health status of the animal(s) involved in the AE prior to their exposure to the VMP.)	Current	VICH Negotiated	All Formats
113	Number of Animals Treated (This is the number of animal(s) being directly treated by the VMP(s).)	Current	VICH Negotiated	All Formats
114	Number of Animals Affected (This is the total number of animals affected in the AER, whether by direct or indirect exposure.)	Current	VICH Negotiated	All Formats
115	Supplemental Documents, including:			
116	Attached Document (These are additional documents containing information relevant to the AE, such as medical record, radiology, clinical chemistry reports, newspaper articles, and letters.)	Current	VICH Negotiated	All Formats
117	Attached Document Filename (This is the name of the document for paper documents or the electronic file for electronic transmissions.)	Current	VICH Negotiated	All Formats
118	Attached Document Type (This is a list of values describing the type of document that is attached, e.g., necropsy report)	Current	VICH Negotiated	All Formats
119	The following data elements are being deleted from the information collection:			
120	2c. Number of Days Between 2a and b:	Deleted		
121	11. Illness/reason for use of this drug	Deleted		

TABLE 3.—DATA ELEMENTS FOR FORM FDA 1932—Continued

Line No.	Data Elements	Current, New, or Deleted Data Element	VICH-Negotiated or FDA-Proposed Data Element	Submission/Transmission Format (Paper Form, Electronic Web-based Rational Questionnaire (EWBRQ), and/or Electronic Gateway-to-Gateway (EGG))
122	17. Did any new illness develop or did initial diagnosis change after suspect drug started?	Deleted		
123	25. Outcome of Reaction to Date - Died	Deleted		
124	26. When reaction appeared, treatment with suspect drug: has already been completed, discontinued, replaced with another drug; continued at altered dose, other (explain)—and the reaction: continued, stopped, recurred, or other (explain)	Deleted		
125	29. Had animal(s) previously reacted to other drugs?	Deleted		
126	30. Has the attending veterinarian seen similar reactions to this drug in any other animals?	Deleted		
127	32. Signature of individual responsible for accuracy of reported information	Deleted		

2. Form FDA 1932a

This section describes data elements on the current Form FDA 1932a and the proposed new data elements. These AE and product and manufacturing defect data elements will be collected electronically, through the MedWatch^{Plus} Portal Rational Questionnaire, and in the paper form. All the data elements will be captured using the MedWatch^{Plus} Portal Rational Questionnaire or the paper form.

Table 4 of this document, entitled ''Data Element Information Collection for Form FDA 1932a,'' presents the data elements the agency is proposing for the collection of animal drug adverse events reports and manufacturing and product problem reports for individuals who choose to report information voluntarily to FDA. The current and proposed new data elements are listed in the column entitled ''Data Elements.'' In general, the information being collected is the same, but the data element has been renamed or restructured to facilitate data collection. As stated previously in this document, the proposed changes are based on FDA's experience in determining the safety and effectiveness of product(s) and need for efficient data capture and entry.

TABLE 4.—DATA ELEMENT INFORMATION COLLECTION FOR FORM FDA 1932A

Line No.	Data Elements	Current or New Data Element
1	Individual Case Safety Report Number (FDA-Assigned Number)	New
2	Date of Initial Report. (This is the date the sender sent the first report of the information.)	New
3	Date Reported (This is the date of this current report.)	Current
4	Submission Type (This is a list of values describing the type of submission, e.g., Initial or Followup Report)	New
5	Report Type (This is a list of values describing the type of information in the report, e.g., adverse event, product problem, or both)	New
6	Manufacturer's Case Number. (The manufacturer's case number is given to the sender by the manufacturer of the product if the sender contacted the manufacturer.)	Current
7	Sender Information (The sender is the person or organization which fills out the report and submits or transmits the report to FDA.), including:	
8	Sender First and Last Name	New
9	Sender Street Address, City, State/Province, Postal/Zip Code, and Country	New
10	Sender Primary and Other Telephone Number, E-Mail Address, and Fax Number	New
11	Sender Category. (This is a list of values describing the role/involvement of the sender, e.g., animal owner, physician, etc.)	New

TABLE 4.—DATA ELEMENT INFORMATION COLLECTION FOR FORM FDA 1932A—Continued

Line No.	Data Elements	Current or New Data Element
12	Did the sender report to other sources?	New
13	Sender also reported to other sources. (This is a list of values describing the sources to which the sender reported the AE or product problem, e.g., manufacturer, distributor, etc.)	New
14	No identity disclosure (This data element indicates whether the sender wants their identity disclosed to the manufacturer.)	Current
15	Preferred Method of Contact. (This is a list of values describing the preferred method of contacting the sender, e.g., telephone, e-mail.)	New
16	Healthcare Professional Information, including:	
17	Healthcare Professional First and Last Name.	Current
18	Healthcare Professional Street Address, City, State/Province, and Postal/Zip Code	Current
19	Healthcare Professional Primary and Other Phone Number	Current
20	Healthcare Professional e-mail address	New
21	Healthcare Professional Country	New
22	Owner's Information (This is the owner of the animal involved in the case.), including:	
23	Owner First and Last Name.	Current
24	Owner Primary and Other Phone Number, and E-Mail Address	New
25	Owner Street Address, City, State/Province, Postal/Zip Code, and Country	New
26	Product Information:	
27	Name of Suspected Product. (This is the name of the product suspected of causing the AE or the product with the product problem.)	Current
28	Name of Manufacturer	Current
29	Lot Number	Current
30	Expiration Date	Current
31	Diagnosis and/or Reason for Use of the Product	Current
32	Product Use Information: Dose Administered (amount of product administered), Interval of Administration (frequency of administration—every 12 hours or for 5 days), and Route of Administration (oral, injection, topical, etc.).	Current
33	Dosage Form. (This is how the product was supplied to the animal, e.g., chewable tablet, topical, injection)	Current
34	Date of First and Last Exposure. (This is the date the product(s) was first administered and last administered to the animal.)	Current
35	Duration of Product Use (Number) and Units of Measurement. (This is the duration the product was given, e.g., 2 weeks.)	New
36	Product Administered By (This is a list of values describing who administered the product(s), e.g., veterinarian/veterinary staff, Owner)	Current
37	Concurrent Drugs Administered (Were concurrent product(s) given to the animal(s)?)	Current
38	Concurrent Products Names. (This is the name of all concurrent products involved in the case.)	Current
39	Animal Information:	
40	Species. (This is a list of values for selecting the species of the animal(s) involved in the case.)	Current
41	Breed and Crossbreed (This is the breed(s) of animal(s) involved in the report.)	Current
42	Gender. (This a list of values for the selection of the gender(s) of animal(s) involved in the AER.)	Current

TABLE 4.—DATA ELEMENT INFORMATION COLLECTION FOR FORM FDA 1932A—Continued

Line No.	Data Elements	Current or New Data Element
43	Reproductive Status. (This is a list of values describing whether the animal is intact, neutered, et cetera.)	Current
44	Age and Age Units	Current
45	Weight and Weight Units	Current
46	Overall Health Status When Suspected Product Given. (This is a list of values describing the health status of the animal(s) involved in the AE prior to their exposure to the product(s).)	Current
47	Number of Animals Treated (This is the number of animal(s) being directly treated by the product(s).)	New
48	Number of Animals Affected. (This is the total number of animals affected in the AER, whether by direct or indirect exposure.)	New
49	Adverse Event Information:	
50	Veterinarian's Level of Suspicion that Product Caused the AE. (This is a list of values describing the veterinarian's level of suspicion, e.g., high, medium, low, or unknown.)	Current
51	Treatment of AE. (This is a description of how the AE was treated.)	Current
52	Did the AE Abate After Stopping the Product?	Current
53	Did the AE Reappear After Reintroduction of the product?	Current
54	Outcome. (This is a list of values describing the overall animal health status after exposure to the product.)	Current
55	Length of Time Between Initial Exposure to Suspected Product and Onset of AE, numeric value and units of measurement	Current
56	Length of Time Between Last Administration of Suspected Product and Onset of AE, numeric value and units of measurement	Current
57	Date of Onset of AE. (This is the date that the first adverse clinical sign(s) occurred.)	New
58	Date of Product Problem Discovery. (This is the date that the product problem was discovered.)	New
59	When the AE Occurred, Treatment with Suspected Product. (This is a list of values describing the use of the suspected product after the AE occurred)	Current
60	Other Relevant Clinical Information:	
61	Concurrent Clinical Problem (Does the animal(s) have concurrent clinical problems?)	Current
62	List Concurrent Clinical Problem(s)	Current
63	AE/Product Problem (Long Narrative) (This is a detailed description of the case.)	Current
64	Supplemental Documents:	
65	Attached Document Name/File name (if electronic) (This is the name of the document for paper documents or the name of the electronic file for electronic transmissions.)	Current
66	Attached Document Type (This is a list of values describing the type of document that is attached, e.g., necropsy report)	Current
67	Attached Document(s) (These are additional documents containing information relevant to the AE, e.g., medical record, radiology, clinical chemistry reports, newspaper articles, and letters.)	Current
68	Attached Document Description. (This is a description of the document.)	New

C. Request for Comments

FDA invites comments on all aspects of the revised collection of the data elements for Forms FDA 1932 and 1932a as set forth in section III.B of this notice, including whether such lists incorporate all data elements necessary to report an adverse event and a product or manufacturing defect, and whether certain data elements should be deleted or modified. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written 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: November 16, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–27956 Filed 11–19–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301/496–7057; *fax:* 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Phage Display Plasmids With Improved Expression Properties for Human and Chimeric Nonhuman/Human Fab Libraries

Description of Invention: The Fab molecule was the first generated antibody fragment and still dominates basic research and clinical applications. New phage display vectors were designed to generate and select Fab libraries with human constant domains. These vectors facilitate bacterial expression of human, humanized, and chimeric nonhuman/human Fab antibody fragments. They differ from currently available pComb3H and pComb3X phage display vectors by assembling human and chimeric nonhuman/human Fab libraries in two rather than three PCR steps. As a result, these novel constructs retain the initial variable light and heavy chain sequences and improve the resulting Fab library's complexity in terms of number, diversity, and affinity. These constructs were developed with and without a His tag and yield approximately 100 μg to 2 mg of protein, which can be used for evaluation and characterization of Fab binding properties such as affinity and specificity. Notably, the His tag provides a handle to easily purify Fab.

Applications

• Generation of human, humanized, and chimeric nonhuman/human Fab antibody fragments.

• Research tool to characterize Fab antibody fragments.

Advantages

• Improved Fab library with complexity and number, diversity, and affinity.

• His tag construct allows for simplified purification assays.

Inventor: Christoph Rader (NCI).

Relevant Publications

1. KY Kwong and C Rader. E. coli expression and purification of Fab antibody fragments. Curr Protoc Protein Sci. 2009 Feb;Chapter 6:Unit 6.10.

2. T Hofer *et al.* Chimeric rabbit/human Fab and IgG specific for members of the Nogo-66 receptor family selected for species cross-reactivity with an improved phage display vector. J Immunol Methods. 2007 Jan 10;318(1–2):75–87.

Patent Status: HHS Reference No. E–008–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Potent and Selective Inhibitors of Human Lipoxygenase for Prostate Cancer Therapy

Description of Invention: With more than $2 billion in revenues in the US in 2007, the market for diagnostic and therapeutic products for prostate cancer is substantial. More than 2,000,000 American men currently live with prostate cancer and more than 200,000 new cases are diagnosed each year.

Researchers led by Dr. David Maloney at the National Human Genome Research Institute (NHGRI) have discovered several novel compounds that selectively and potently inhibit lipoxygenase (LOX), an enzyme that metabolizes polyunsaturated fatty acids which has been implicated in the pathogenesis of prostate cancers. These novel compounds are small molecules, and as such have an advantage over antibody-based technologies in this market. As prostate cancer is the most commonly diagnosed malignancy among men in the USA and Europe, the significant need for new therapies suggests that these novel LOX inhibitor compounds have a strong potential of reaching the marketplace.

Applications

• Therapeutics for prostate cancer.

• Therapeutics for several other LOX-associated pathologies including atherosclerosis, asthma, other cancers, glomerulonephritis, osteoporosis, and Alzheimer's disease.

Advantages

• Potent and selective inhibitory activity to reduce negative side effects.

• Compounds are small molecules (less immunogenic than antibodies).

Development Status: Pre-clinical.

Inventors: David Maloney *et al.* (NHGRI).

Relevant Publications

1. V Kenyon *et al.* Novel human lipoxygenase inhibitors discovered using virtual screening with homology models. J Med Chem. 2006 Feb 23;49(4):1356–1363.

2. JD Deschamps *et al.* Baicalein is a potent in vitro inhibitor against both reticulocyte 15-human and platelet 12-human lipoxygenases. Bioorg Med Chem. 2006 Jun 15;14(12):4295–4301.

3. Y Vasquez-Martinez *et al.* Structure-activity relationship studies of flavonoids as potent inhibitors of human platelet 12-hLO, reticulocyte 15-hLO–1, and prostate epithelial 15-hLO–2. Bioorg Med Chem. 2007 Dec 1;15(23):7408–7425.

4. J Inglese *et al.* Quantitative high-throughput screening: a titration-based approach that efficiently identifies biological activities in large chemical libraries. Proc Natl Acad Sci USA. 2006 Aug 1;103(31): 11473–11478.

Patent Status: U.S. Provisional Application No. 61/238,972 filed 01 Sep 2009 (HHS Reference No. E–252–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Patrick P. McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov.*

Collaborative Research Opportunity: The NIH Chemical Genomics Center, NHGRI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please