TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.47(a)(3)	1,945	12.03	23,400	0.17 (10 minutes)	3,978
610.47(b)(3)	4,961	0.41	2,050	1	2,050
630.6(a) [3]	648	668.72	433,333	0.08 (5 minutes)	34,667
630.6(a) [4]	84	53.57	4,500	1.5 (90 minutes)	6,750
630.6(d)(1)	63	35.71	2,250	1	2,250
Total					61,043

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of establishments that fall under CLIA that transfuse blood and components and FDA-registered blood establishments (0.05 × 4,961 + 2,361 = 366).
[3] Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[4] Notification of donors deferred based on reactive test results for evidence of infection due to communicable disease agents.

Dated: February 25, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–04381 Filed 3–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1721]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Applications

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 April 2, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0014. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

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.

Investigational New Drug (IND) Regulations—21 CFR Part 312 (OMB Control Number 0910–0014)—Extension

FDA is requesting OMB approval for the reporting and recordkeeping requirements contained in FDA regulations entitled ''Investigational New Drug Application'' in part 312 (21 CFR part 312). Part 312 implements provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) to issue regulations under which the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products can be conducted.

FDA is charged with implementing statutory requirements that drug products marketed in the United States be shown to be safe and effective, properly manufactured, and properly labeled for their intended uses. Section 505(a) of the FD&C Act provides that a new drug may not be introduced or delivered for introduction into interstate commerce in the United States unless FDA has previously approved a new drug application (NDA). FDA approves an NDA only if the sponsor of the application first demonstrates that the drug is safe and effective for the conditions prescribed, recommended, or suggested in the product's labeling. Proof must consist, in part, of adequate and well-controlled studies, including studies in humans, that are conducted by qualified experts. The IND regulations establish reporting requirements that include an initial application as well as amendments to that application, reports on significant revisions of clinical investigation plans, and information on a drug's safety or effectiveness. In addition, the sponsor is required to give FDA an annual summary of the previous year's clinical experience.

Submissions are reviewed by medical officers and other Agency scientific reviewers assigned responsibility for overseeing the specific study. The IND regulations also contain recordkeeping requirements that pertain to the responsibilities of sponsors and investigators. The detail and complexity of these requirements are dictated by the scientific procedures and human subject safeguards that must be followed in the clinical tests of investigational new drugs.

The IND information collection requirements provide the means by which FDA can monitor the clinical investigation of the safety and effectiveness of unapproved new drugs and biological products, including the following: (1) Monitor the safety of ongoing clinical investigations; (2) determine whether the clinical testing of a drug should be authorized; (3) ensure production of reliable data on the metabolism and pharmacological action of the drug in humans; (4) obtain timely information on adverse reactions to the drug; (5) obtain information on side effects associated with increasing doses; (6) obtain information on the drug's effectiveness; (7) ensure the design of well-controlled, scientifically valid studies; and (8) obtain other information pertinent to determining whether clinical testing should be continued, and information related to the protection of human subjects. Without the information provided by industry as required under the IND regulations, FDA cannot authorize or monitor the clinical investigations which must be conducted prior to authorizing the sale and general use of new drugs. These reports enable FDA to monitor a study's

progress, to assure subject safety, to assure that a study will be conducted ethically, and to increase the likelihood that the sponsor will conduct studies that will be useful in determining whether the drug should be marketed and available for use in medical practice.

There are two forms that are required under part 312:

Form FDA–1571—''Investigational New Drug Application.'' A person who intends to conduct a clinical investigation submits this form to FDA. It includes the following information:

(1) A cover sheet containing background information on the sponsor and investigator;

(2) A table of contents;

(3) An introductory statement and general investigational plan;

(4) An investigator's brochure describing the drug substance;

(5) A protocol for each planned study;

(6) Chemistry, manufacturing, and control information for each investigation;

(7) Pharmacology and toxicology information for each investigation; and

(8) Previous human experience with the investigational drug.

Form FDA–1572—''Investigator Statement.'' Before permitting an investigator to begin participation in an investigation, the sponsor must obtain and record this form. It includes background information on the investigator and the investigation, and a general outline of the planned investigation and the study protocol.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements in part 312.

I. Reporting Requirements

Section 312.2(e)—Requests for FDA advice on the applicability of part 312 to a planned clinical investigation.

Section 312.6—Labeling of an investigational new drug. Estimates for the information collection in this requirement are included under § 312.23(a)(7)(iv)(d).

Section 312.8—Charging for investigational drugs under an IND.

Section 312.10—Applications for waiver of requirements under part 312. As indicated in § 312.10(a), estimates for the information collection in this requirement are included under §§ 312.23 and 312.31. In addition, other waiver requests under § 312.10 are estimated in table 1.

Section 312.20(c)—Applications for investigations involving an exception from informed consent under § 50.24 (21 CFR 50.24). Estimates for the information collection in this requirement are included under § 312.23.

Section 312.23—IND (content and format).

Section 312.23(a)(1)—Cover sheet FDA–1571.

Section 312.23(a)(2)—Table of Contents.

Section 312.23(a)(3)—Investigational plan for each planned study.

Section 312.23(a)(5)—Investigator's brochure.

Section 312.23(a)(6)—Protocols—Phase 1, 2, and 3.

Section 312.23(a)(7)—Chemistry, manufacturing, and control information.

Section 312.23(a)(7)(iv)(a),(b),(c)—A description of the drug substance, a list of all components, and any placebo used.

Section 312.23(a)(7)(iv)(*d*)—Labeling: Copies of labels and labeling to be provided each investigator.

Section 312.23(a)(7)(iv)(*e*)—Environmental impact analysis regarding drug manufacturing and use.

Section 312.23(a)(8)—Pharmacological and toxicology information.

Section 312.23(a)(9)—Previous human experience with the investigational drug.

Section 312.23(a)(10)—Additional information.

Section 312.23(a)(11)—Relevant information.

Section 312.23(f)—Identification of exception from informed consent.

Section 312.30—Protocol amendments.

§ 312.30(a)—New protocol

§ 312.30(b)—Changes in protocol

§ 312.30(c)—New investigator.

§ 312.30(d)—Content and format.

§ 312.30(e)—Frequency.

Section 312.31—Information amendments.

§ 312.31(b)—Content and format.

— Chemistry, toxicology, or technical information.

Section 312.32—Safety reports.

§ 312.32(c)(1)—Written reports to FDA and to investigators.

§ 312.32(c)(2)—Telephone reports to FDA for fatal or life-threatening experience.

§ 312.32(c)(3)—Format or frequency.

§ 312.32(d)—Followup submissions.

Section 312.33—Annual reports.

§ 312.33(a)—Individual study information.

§ 312.33(b)—Summary information.

§ 312.33(b)(1)—Adverse experiences.

§ 312.33(b)(2)—Safety report summary.

§ 312.33(b)(3)—List of fatalities and causes of death.

§ 312.33(b)(4)—List of discontinuing subjects.

§ 312.33 (b)(5)—Drug action.

§ 312.33 (b)(6)—Preclinical studies and findings.

§ 312.33 (b)(7)—Significant changes.

§ 312.33(c)—Next year general investigational plan.

§ 312.33(d)—Brochure revision.

§ 312.33(e)—Phase I protocol modifications.

§ 312.33(f)—Foreign marketing developments.

Section 312.38(b) and (c)—Notification of withdrawal of an IND.

Section 312.41—Comment and advice on an IND. Estimates for the information collection in this requirement are included under § 312.23.

Section 312.42—Sponsor requests that a clinical hold be removed, and submits a complete response to the issues identified in the clinical hold order.

Section 312.44(c) and (d)—Opportunity for sponsor response to FDA when IND is terminated.

Section 312.45(a) and (b)—Sponsor request for, or response to, an inactive status determination of an IND.

Section 312.47—Meetings, including ''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings.

Section 312.48—Dispute resolution. Estimates for the information collection in this requirement are included under § 312.47.

Section 312.53(c)—Investigator information. Investigator report (Form FDA–1572) and narrative; Investigator's background information; Phase 1 outline of planned investigation and Phase 2 outline of study protocol.

Section 312.54(a) and (b)—Sponsor submissions concerning investigations involving an exception from informed consent under § 50.24.

§ 312.55(b)—Sponsor reports to investigators on new observations, especially adverse reactions and safe use. Only ''new observations'' are estimated under this section; investigator brochures are included under § 312.23.

Section 312.56(b), (c), and (d)—Sponsor monitoring of all clinical investigations, investigators, and drug safety; notification to FDA and others.

Section 312.58(a)—Sponsor's submission of records to FDA on request.

Section 312.64—Investigator reports to the sponsor.

§ 312.64(a)—Progress reports.

§ 312.64(b)—Safety reports

§ 312.64(c)—Final reports.

§ 312.64(d)—Financial disclosure

reports.

Section 312.66—Investigator reports to institutional review board (IRB). Estimates for the information collection in this requirement are included under § 312.53.

Section 312.70—Investigator disqualification; opportunity to respond to FDA.

Section 312.83—Sponsor submission of treatment protocol. Estimates for this requirement are included under § 312.320.

Section 312.85—Sponsors conducting phase 4 studies. Estimates for the information collection in this requirement are included under § 312.23, and under §§ 314.50, 314.70, and 314.81 in OMB control number 0910–0001.

Section 312.110(b)—Requests to export an investigational drug.

Section 312.120—Submissions related to foreign clinical studies not conducted under an IND.

Section 312.130—Requests for disclosable information in an IND and from investigations involving an exception from informed consent under § 50.24.

Sections 312.310(b); 312.305(b)—Submissions related to expanded access and treatment of an individual patient.

Section 312.310(d)—Submissions related to emergency use of an investigational new drug.

Sections 312.315(c); 312.305(b)—Submissions related to expanded access and treatment of an intermediate-size patient population.

Section 312.320—Submissions related to a treatment IND or treatment protocol.

II. Recordkeeping Requirements

Section 312.52(a)—Transfer of obligations to a contract research organization.

Section 312.57—Sponsor recordkeeping on the investigational drug.

Section 312.59—Sponsor recordkeeping of disposition of unused supply of drugs. Estimates for the information collection in this requirement are included under § 312.57.

Section 312.62(a)—Investigator recordkeeping of disposition of drugs.

Section 312.62(b)—Investigator recordkeeping of case histories of individuals.

Section 312.120(d)—Recordkeeping requirements for submissions related to foreign clinical studies not conducted under an IND. Estimates for the information collection in this requirement are included under § 312.57.

Section 312.160(a)(3)—Records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.

Section 312.160(c)—Shipper records of alternative disposition of unused drugs.

In the **Federal Register** of November 5, 2014 (79 FR 65663), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 24 comments, however, these comments did not address the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
312.2(e), Requests for FDA advice on the applicability of part 312 to a planned clinical investigation	800	1	800	24	19,200
312.8, Requests to charge for an investigational drug	56	1.25	70	48	3,360
312.10, Requests to waive a requirement in part 312	50	1.76	88	24	2,112
312.23(a) through (f), IND content and format (including Form FDA 1571)	1,689	1.57	2,648	1,600	4,236,800
312.30(a) through (e), Protocol amendments	3,739	5.77	21,588	284	6,130,992
312.31 (b), Information amendments	4,537	3.39	15,377	100	1,537,700
312.32(c) and (d), IND Safety reports	755	24.28	18,332	32	586,624
312.33(a) through (f), IND Annual reports	2,877	2.76	7,953	360	2,863,080
312.38(b) and (c), Notifications of withdrawal of an IND	862	1.54	1,328	28	37,184
312.42, Sponsor requests that a clinical hold be removed, including sponsor submission of a complete response to the issues identified in the clinical hold order	158	1.30	205	284	58,220
312.44(c) and (d), Sponsor responses to FDA when IND is terminated	12	1	12	16	192
312.45(a) and (b), Sponsor requests for or responses to an inactive status determination of an IND by FDA	260	1.73	451	12	5,412
312.47, Meetings, including ''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings	225	1.86	419	160	67,040
312.53(c), Investigator reports submitted to the sponsor, including Form FDA 1572, curriculum vitae, clinical protocol, and financial disclosure. (Third party disclosure)	1,444	8.38	12,087	80	966,960
312.54(a), Sponsor submissions to FDA concerning investigations involving an exception from informed consent under 21 CFR 50.24	7	5	35	48	1,680
312.54(b), Sponsor notifications to FDA and others concerning an IRB determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a). (Includes third party disclosure)	7	1	7	48	336
312.55(a), Investigator brochures submitted by the sponsor to each investigator. (Third party disclosure)	590	3.50	2,067	48	99,216

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
312.55(b), Sponsor reports to investigators on new observations, especially adverse reactions and safe use. (Third party disclosure)	590	3.50	2,067	48	99,216
312.56(b),(c), and (d), Sponsor notifications to FDA and others resulting from: (1) The sponsor's monitoring of all clinical investigations and determining that an investigator is not in compliance with the investigation agreements; (2) the sponsor's review and evaluation of the evidence relating to the safety and effectiveness of the investigational drug; and (3) the sponsor's determination that the investigational drug presents an unreasonable and significant risk to subjects. (Includes third party disclosure)	3,584	6.52	23,355	80	1,868,400
312.58(a), Sponsor's submissions of clinical investigation records to FDA on request during FDA inspections	60	1	60	8	480
312.64, Investigator reports to the sponsor, including progress reports, safety reports, final reports, and financial disclosure reports. (Third party disclosure)	1,444	1	1,444	24	34,656
312.70, During the disqualification process of a clinical investigator by FDA, the number of investigator responses or requests to FDA following FDA's notification to an investigator of its failure to comply with investigation requirements	4	1	4	40	160
312.110(b)(4) and (b)(5), Written certifications and written statements submitted to FDA relating to the export of an investigational drug	11	26.28	289	75	21,675
312.120(b), Submissions to FDA of ''supporting information'' related to the use of foreign clinical studies not conducted under an IND	1,414	8.63	12,198	32	390,336
312.120(c), Waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	35	2.34	82	24	1,968
312.130, Requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	3	1	3	8	24
312.310(b) and 312.305(b), Submissions related to expanded access and treatment of an individual patient	228	1.76	401	8	3,208
312.310(d), Submissions related to emergency use of an investigational new drug	410	2.19	899	16	14,384
312.315(c) and 312.305(b), Submissions related to expanded access and treatment of an intermediate-size patient population	44	7.07	311	120	37,320
312.320(b), Submissions related to a treatment IND or treatment protocol	12	12.67	152	300	45,600
Total					19,134,039

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
312.52(a), Sponsor records for the transfer of obligations to a contract research organization	335	1.50	503	2	1,006
312.57, Sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug, and any financial interests	1,689	1	1,689	100	168,900
312.62(a), Investigator recordkeeping of the disposition of drugs	1,444	1	1,444	40	57,760
312.62(b), Investigator recordkeeping of case histories of individuals	1,444	1	1,444	40	57,760
312.160(a)(3), Records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests	547	1.40	782	* 0.50	391
312.160(c), Shipper records of alternative disposition of unused drugs	547	1.40	782	* 0.50	391

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Total					286,190

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* Thirty (30) minutes.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
312.2(e), Requests for FDA advice on the applicability of part 312 to a planned clinical investigation	217	1.18	255	24	6,120
312.8, Requests to charge for an investigational drug	20	1.50	30	48	1,440
312.10, Requests to waive a requirement in part 312	2	1	2	24	48
312.23(a) through (f), IND content and format	335	1.35	452	1,600	723,200
312.30(a) through (e), Protocol amendments	694	5.84	4,050	284	1,150,200
312.31(b), Information amendments	77	2.43	187	100	18,700
312.32(c) and (d), IND Safety reports	161	8.83	1,421	32	45,472
312.33(a) through (f), IND Annual reports	745	2.14	1,595	360	574,200
312.38(b) and (c), Notifications of withdrawal of an IND	134	1.69	227	28	6,356
312.42, Sponsor requests that a clinical hold be removed, including sponsor submission of a complete response to the issues identified in the clinical hold order	67	1.30	87	284	24,708
312.44(c) and (d), Sponsor responses to FDA when IND is terminated	34	1.15	39	16	624
312.45(a) and (b), Sponsor requests for or responses to an inactive status determination of an IND by FDA	55	1.38	76	12	912
312.47, Meetings, including ''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings	88	1.75	154	160	24,640
312.53(c), Investigator reports submitted to the sponsor, including Form FDA–1572, curriculum vitae, clinical protocol, and financial disclosure	453	6.33	2,869	80	229,520
312.54(a), Sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	1	1	1	48	48
312.54(b), Sponsor notifications to FDA and others concerning an IRB determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	1	1	1	48	48
312.55(a), Number of investigator brochures submitted by the sponsor to each investigator	239	1.91	457	48	21,936
312.55(b), Number of sponsor reports to investigators on new observations, especially adverse reactions and safe use	243	4.95	1,203	48	57,744
312.56(b), (c), and (d), Sponsor notifications to FDA and others resulting from: (1) The sponsor's monitoring of all clinical investigations and determining that an investigator is not in compliance with the investigation agreements; (2) the sponsor's review and evaluation of the evidence relating to the safety and effectiveness of the investigational drug; and (3) the sponsor's determination that the investigational drug presents an unreasonable and significant risk to subjects	108	2.21	239	80	19,120
312.58(a), Number of sponsor's submissions of clinical investigation records to FDA on request during FDA inspections	7	1	7	8	56
312.64, Number of investigator reports to the sponsor, including progress reports, safety reports, final reports, and financial disclosure reports	2,728	3.82	10,411	24	249,864
312.70, During the disqualification process of a clinical investigator by FDA, the number of investigator responses or requests to FDA following FDA's notification to an investigator of its failure to comply with investigation requirements	5	1	5	40	200
312.110(b)(4) and (b)(5), Number of written certifications and written statements submitted to FDA relating to the export of an investigational drug	18	1	18	75	1,350

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
312.120(b), Number of submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	280	9.82	2,750	32	88,000
312.120(c), Number of waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	7	2.29	16	24	384
312.130, Number of requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	350	1.34	470	8	3,760
312.310(b) and 312.305(b), Number of submissions related to expanded access and treatment of an individual patient	78	1.08	84	8	672
312.310(d), Number of submissions related to emergency use of an investigational new drug	76	2.76	210	16	3,360
312.315(c) and 312.305(b), Number of submissions related to expanded access and treatment of an intermediate-size patient population	9	1	9	120	1,080
312.320(b), Number of submissions related to a treatment IND or treatment protocol	1	1	1	300	300
Total					3,254,062

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
312.52(a), Sponsor records for the transfer of obligations to a contract research organization	75	1.40	105	2	210
312.57, Sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug, and any financial interests	335	2.70	904	100	90,400
312.62(a), Investigator recordkeeping of the disposition of drugs	453	1	453	40	18,120
312.62(b), Investigator recordkeeping of case histories of individuals	453	1	453	40	18,120
312.160(a)(3), Records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests	111	1.40	155	*0.50	78
312.160(c), Shipper records of alternative disposition of unused drugs	111	1.40	155	*0.50	78
Total					127,006

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* Thirty (30) minutes.

Dated: February 24, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–04379 Filed 3–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0430]

Measuring Dystrophin in Dystrophinopathy Patients and Interpreting the Data; Public Scientific Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public scientific workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public scientific workshop to discuss dystrophin protein quantification methodologies for human tissue. This workshop is being cosponsored by the National Institutes of Health (NIH). The purpose of the workshop is to discuss currently available methodologies and to identify scientific knowledge gaps and opportunities for improving dystrophin protein detection in the context of drug development. The intended audiences for this workshop are scientists and clinicians involved in the acquisition, measurement, and analysis of proteins associated with Duchenne Muscular Dystrophy (DMD).