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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–20QS; Docket No. CDC–2020–0086]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Multi-site Clinical Assessment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (MCAM). This collection is designed to assess and characterize illness heterogeneity of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), and uses a standardized approach including standardized protocols with standardized tests and instruments to collect data on patients from multiple clinical practices.

DATES: CDC must receive written comments on or before October 2, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0086 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7118; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Multi-site Clinical Assessment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (MCAM)—Existing collection in use without an OMB Control Number—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This Multi-site Clinical Assessment of Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (MCAM) study uses a standardized approach for data collection to examine the heterogeneity of patients with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) using a clinical epidemiologic longitudinal study with a retrospective and prospective rolling cohort design. The study also aims to address the issue of ME/CFS case definition and improve measures of illness domains by using evidence-based data from multiple clinical practices in the United States. Healthy adults and those with illnesses that share some features with ME/CFS were enrolled in comparison groups. Children and adolescents with ME/CFS and healthy participants were also enrolled.

The MCAM study has been conducted in multiple stages following multiple study protocols. The time burden estimates are based on the 2012–2019 data collection, which is the most recent stage of data collection completed.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Adult	CDC Symptom Inventory (CDC–SI)/Form A	45	1	12/60	9
Adult	CDC Symptom Inventory (CDC–SI)/Form B	20	1	10/60	3
Adult	CDC Symptom Inventory (CDC–SI)	20	1	8/60	3
Adult	Short Form CDC–SI/Checklist	85	1	10/60	14
Adult	Medical Outcomes Study Short Form 36	85	1	7/60	10

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Adult	Multidimensional Fatigue Inventory (MFI–20)	85	1	5/60	7
Adult	DePaul Symptom Questionnaire (DSQ)	45	1	24/60	18
Adult	DSQ, 26 selected questions	65	1	12/60	13
Adult	DSQ, 18 selected questions	85	1	6/60	9
Adult	PROMIS Short Form (PROMIS SF—Fatigue, SD, SRI, PB, PI) & Sleep Data Collection Form.	85	1	5/60	7
Adult	PROMIS SF—Fatigue, SD, SRI, PB, PI	85	1	4/60	6
Adult	Brief Pain Inventory (BPI)	85	1	13/60	18
Adult	Patient Health Questionnaire (PHQ–8), Generalized Anxiety Disorder (GAD–7), CDC Health-Related Quality of Life (HRQoL–4).	85	1	10/60	14
Adult	CDC HRQoL–4	85	1	3/60	4
Adult	CDC HRQoL–4 with activity limitation questions	85	1	4/60	6
Adult	Self-Rating Depression Scale (SDS)	45	1	7/60	5
Adult	Illness Impact Questionnaire	85	1	3/60	4
Adult	Saliva Data Collection Sheet	85	1	5/60	7
Adult	Orthostatic Grading Scale (OGS)	85	1	3/60	4
Adult	COMPosite Autonomic Symptom Score 31 (COMPASS–31).	85	1	5/60	7
Adult	CDC Symptom Inventory (CDC–SI)/Form A	24	1	42/60	17
Adult	CDC Symptom Inventory (CDC–SI)/Form B	30	1	20/60	10
Adult	CDC Symptom Inventory (CDC–SI)	15	1	10/60	3
Adult	Short Form CDC–SI/Checklist	69	1	20/60	23
Adult	Medical Outcomes Study Short Form 36	69	1	17/60	20
Adult	Multidimensional Fatigue Inventory (MFI–20)	69	1	10/60	12
Adult	DePaul Symptom Questionnaire (DSQ)	24	1	36/60	14
Adult	DSQ, 26 selected questions	45	1	18/60	14
Adult	DSQ, 18 selected questions	69	1	20/60	23
Adult	PROMIS Short Form (PROMIS SF—Fatigue, SD, SRI, PB, PI) & Sleep Data Collection Form.	24	1	6/60	2
Adult	PROMIS SF—Fatigue, SD, SRI, PB, PI	69	1	5/60	6
Adult	Brief Pain Inventory (BPI)	24	1	13/60	5
Adult	Patient Health Questionnaire (PHQ–8), Generalized Anxiety Disorder (GAD–7), CDC Health-Related Quality of Life (HRQoL–4).	24	1	10/60	4
Adult	CDC HRQoL–4	69	1	4/60	5
Adult	CDC HRQoL–4 with activity limitation questions	69	1	7/60	8
Adult	Self-Rating Depression Scale (SDS)	24	1	7/60	3
Adult	Illness Impact Questionnaire	69	1	3/60	3
Adult	Saliva Data Collection Sheet	69	1	5/60	6
Adult	Orthostatic Grading Scale (OGS)	69	1	5/60	6
Adult	COMPosite Autonomic Symptom Score 31 (COMPASS–31).	69	1	7/60	8
Pediatric	CDC Symptom Inventory: For Baseline Subjects Pediatrics.	36	1	8/60	5
Pediatric	CDC Symptom Inventory: For the Follow-Up Subjects Pediatrics.	29	1	6/60	3
Pediatric	SF–36 Health Survey	64	1	5/60	5
Pediatric	Multidimensional Fatigue Inventory (MFI–20)	64	1	2/60	2
Pediatric	Selected Questions from DePaul Pediatric Health Questionnaire (DPHQ), 19 Questions.	64	1	5/60	5
Pediatric	PROMIS Pediatric Instruments (Fatigue & Pain)	64	1	2/60	2
Pediatric	Pediatric Pain Questionnaire (PPQ)	64	1	7/60	8
Pediatric	Visual Analogue Scale	64	1	6/60	6
Pediatric	Hospital Anxiety and Depression Scale	64	1	5/60	5
Pediatric	Pediatric Daytime Sleepiness Scale	64	1	2/60	2
Pediatric	Social Participation Form Pediatric	64	1	7/60	8
Pediatric	Sociability Form	64	1	3/60	3
Pediatric	Saliva Collection Form	64	1	5/60	5
Pediatric	CDC Symptom Inventory: For Baseline Subjects Pediatrics.	3	1	20/60	1
Pediatric	CDC Symptom Inventory: For the Follow-Up Subjects Pediatrics.	3	1	9/60	0
Pediatric	SF–36 Health Survey	3	1	9/60	0
Pediatric	Multidimensional Fatigue Inventory (MFI–20)	3	1	7/60	0
Pediatric	Selected Questions from DePaul Pediatric Health Questionnaire (DPHQ), 19 Questions.	3	1	10/60	0
Pediatric	PROMIS Pediatric Instruments (Fatigue & Pain)	3	1	3/60	0

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pediatric	Pediatric Pain Questionnaire (PPQ)	3	1	15/60	1
Pediatric	Visual Analogue Scale	3	1	8/60	0
Pediatric	Hospital Anxiety and Depression Scale	3	1	7/60	0
Pediatric	Pediatric Daytime Sleepiness Scale	3	1	3/60	0
Pediatric	Social Participation Form Pediatric	3	1	10/60	0
Pediatric	Sociability Form	3	1	5/60	0
Pediatric	Saliva Collection Form	3	1	5/60	0
Adult	CogState Practice Section	109	1	17/60	31
Adult	CogState Baseline Section	109	1	27/60	49
Adult	WAIS IV DS F+B, TOPF	109	1	10/60	18
Adult	Exercise (Bike) Testing	64	1	30/60	32
Adult	CogState Time 1 Section	109	1	22/60	40
Adult	CogState Time 2 Section	109	1	12/60	22
Adult	CogState Time 3 Section	109	1	12/60	22
Adult	CogState Time 4 Section	109	1	12/60	22
Adult	Visual Analogue Scale for CFS Symptoms	60	1	8/60	8
Adult	EQ–5D–Y Health Questionnaire	60	1	6/60	6
Adult	PROMIS SF v1—Physical Function	60	1	5/60	5
Adult	Physical Fitness and Exercise Activity Levels of Scale	60	1	2/60	2
Adult	International Physical Activity Questionnaire (Self-Administered Long Form).	60	1	5/60	5
Adult	Physical Activity Readiness Questionnaire	60	1	5/60	5
Adult	Visual Analogue Scale for CFS Symptoms	49	1	8/60	6
Adult	EQ–5D–Y Health Questionnaire	49	1	6/60	5
Adult	PROMIS SF v1—Physical Function	49	1	5/60	4
Adult	Physical Fitness and Exercise Activity Levels of Scale	49	1	2/60	2
Adult	International Physical Activity Questionnaire (Self-Administered Long Form).	49	1	5/60	4
Adult	Physical Activity Readiness Questionnaire	49	1	5/60	4
Total		715			

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0806]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2021

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for fiscal year (FY) 2021 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2018 (ADUFA IV), authorizes FDA to collect user fees for certain animal drug applications and supplements, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2021.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov.* For general questions, you may also email the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplements; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FYs 2019 through 2023, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)(2) and (3)). Beginning with FY 2021, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections or to account for certain collection shortfalls. (21 U.S.C. 379j–12(c)(3) and (g)(5)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) Revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of