OMB Burden Statement for FDA Form 2511 and 2512

OMB Approval No. 0910-0027; Exp. Date: 09/30/2020

FORM FDA 2511

Public reporting burden for this collection of information is estimated to average 0.2 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 2512

Public reporting burden for this collection of information is estimated to average 0.33 hour per response for new submissions, 0.17 hour per response for amendments, and 0.1 hour per response for notices of discontinuances, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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