

**FDA DOCUMENTATION FOR THE GENERIC CLEARANCE
OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL
RESEARCH (0910-0847)**

TITLE OF INFORMATION COLLECTION:

Collection of Data to Support “Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Physician Experiences with REMS Programs”

As requested, to facilitate the review of changes, below is a summary of changes made to the three related PRA packages for the REMS surveys/interviews:

1. REMS physician surveys – approved by OMB on 12/10/21

- addition of five questions added to address the unanticipated pandemic impact (experience before and during the pandemic) to the isotretinoin, lenalidomide, ambrisentan, bosentan, and clozapine survey documents:

“D1. Did you prescribe isotretinoin prior to the start of the COVID-19 pandemic in March 2020?”

£₁ Yes

£₂ No

D2. IF YOU ANSWERD NO TO D1, SKIP TO D3. IF YOU ANSWERED YES TO D1, please rate how much easier or harder it was to complete the following tasks related to prescribing ambrisentan during vs. before the pandemic.

	Much easier	Somewhat easier	Neither easier nor harder	Somewhat harder	Much harder
a. The patient enrollment process	£ ₁	£ ₂	£ ₃	£ ₄	£ ₅
b. Testing patients	£ ₁	£ ₂	£ ₃	£ ₄	£ ₅
c. Reporting testing findings	£ ₁	£ ₂	£ ₃	£ ₄	£ ₅

D3. Were you aware of the pandemic policy related to required testing under special FDA drug safety programs?

£₁ Yes

£₂ No

In March 2020, the FDA announced it would permit drug manufacturers and health care providers to make accommodations for laboratory tests required under the drug safety programs during the COVID-19 pandemic, such as allowing patients to take home pregnancy tests instead of using a blood test.

D4. Did the manufacturers of isotretinoin change the drug’s pregnancy testing requirements in response to the pandemic?

- £₁ Yes
- £₂ No
- £₃ I don’t know

D5. Did you change pregnancy testing requirements for your patients taking isotretinoin in response to the pandemic (independent of the drug manufacturers)?

- £₁ Yes (If yes, describe briefly: _____)
- £₂ No”

- addition of two questions added to address the unanticipated pandemic impact (experience before and during the pandemic) to the sodium oxybate survey document:

“D1. Did you prescribe sodium oxybate prior to the start of the COVID-19 pandemic in March 2020?

- £₁ Yes
- £₂ No

D2. IF YOU ANSWERED NO TO D1, SKIP TO E1. IF YOU ANSWERED YES TO D1, please rate how much easier or harder it was to complete the following tasks related to prescribing sodium oxybate during vs. before the pandemic.

	Much easier	Somewhat easier	Neither easier nor harder	Somewhat harder	Much harder
a. The patient enrollment process	£ ₁	£ ₂	£ ₃	£ ₄	£ ₅
b. Monitoring patients	£ ₁	£ ₂	£ ₃	£ ₄	£ ₅
c. Reporting testing findings	£ ₁	£ ₂	£ ₃	£ ₄	£ ₅

“

- Minor wording edits to all of the aforementioned survey documents

2. REMS physician interviews – approved by OMB on 1/13/22

- Very minor word addition to one question (addition of term “myocardial infarction” to specific the risk of harm at issue)
- Very minor non-substantive copy edits: information will “be” publicly released; deleted dangling parentheses

3. REMS patient interviews - approved by OMB on 11/2/21

- Minor wording edits to the patient interview guide and three questions added to address the pandemic impact (regarding their experience before and during the pandemic):

“

1. **IF NOT TAKING DRUG PRE-PANDEMIC: SKIP TO 25. IF TAKING DRUG PRE-PANDEMIC:**
How did your experience with the drug safety program compare before and during the pandemic?
 - a. Undergoing exams and testing [if applicable]
 - b. Accessing medication
 - c. Getting questions answered
 - d. Identifying or responding to side effects or other medical problems

[FOR ALL DRUGS EXCEPT SODIUM OXYBATE]

2. Were you aware of the FDA's special pandemic policy related to required testing under REMS programs? **IF NO: SKIP TO 26. IF YES:**
 - a. Can you explain your understanding of it?
 - b. How were you made aware?
3. In March 2020, the FDA announced it would permit drug manufacturers and health care providers to make accommodations for laboratory tests required under REMS programs during the COVID-19 pandemic, such as allowing patients to have blood and urine tests one every two months instead of once a month. What do you think about the policy?"
 - Minor word edits to the following documents : patient interview – recruitment messages-rally-patient only; patient interview-recruitment messages-rally-patient or caretaker; patient interview-recruitment messages-email-patient or caretaker; patient interview-recruitment messages-email forward-patient only; patient interview-recruitment messages-email forward-patient or caretaker; patient interview-recruitment messages-email-patient only

Date(s) to be conducted:

The sponsor will conduct the physician surveys between 2/14/2022 and 12/31/2022 and conduct the full study between 2/14/2022 and 6/30/2023.

REQUESTED APPROVAL DATE: February 2022

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