

## U.S. Food and Drug Administration

## Targeted Mechanism of Action Presentations in Prescription Drug Promotion

OMB Control Number 0910-0908

Expiration Date: November 30, 2025

## No Material or Non-Substantive Change to a Currently Approved Collection (83-C)

FDA is proposing modifications to the approved information collection study questionnaire based on findings from pretesting and in accordance with the terms of clearance. The revised questionnaire is attached, and the proposed changes to the study questions are also summarized below. FDA is not requesting changes to the burden hours for this information collection.

- Q7, Q8, Q9, Q10, Q11 – remove the response option “Don’t know”
- Q9 – change the question text from “LEYTROL attaches to the Nectin-4 protein on cancer cells only” to “LEYTROL only attaches to cancer cells.”
- Q11 – change the question text from “LEYTROL targets any cell in the body (healthy or cancerous) that has the specific Nectin-4 protein” to “LEYTROL targets both healthy cells and cancer cells if they have a specific protein called Nectin-4.”
- Add two response items to Q35:
  - Q35\_C5. Most medicines are addictive.
  - Q35\_C6. All medicines are poisons.