Any routes of administration for all drug classes are included.

- Bronchodilators
  a. *Beta-adrenergic receptor agonists:* Albuterol, arformoterol, formoterol, indaceterol, levalbuterol, olodaterol, terbutaline, vilanterol
  b. *Antimuscarinics:* Aclidinium, atropine, glycopyrrolate, ipratropium, scopolamine, tiotropium, umeclidinium
  c. *Methylxanthines:* Theophylline, aminophylline, caffeine
- Nebulized saline
- *Corticosteroids:* Beclomethasone, betamethasone, budesonide, ciclesonide, dexamethasone, flunisolide, fluticasone, hydrocortisone, methylprednisolone, mometasone, prednisone
- *Diuretics:* Amiloride, bumetanide, ethacrynic acid, furosemide, hydrochlorothiazide, indapinide, metolazone, spironolactone, torsemide, triamterine
- Lidocaine
- *Non-steroidal anti-inflammatory agents:* Celecoxib, diclofenac, diflusinal, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, ketorolac, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, salsalate, sulindac, tolmetin
- *Phenothiazines:* Promethazine, prochlorperazine, chlorpromazine, thioridazine
- *Atypical antipsychotics:* Aripiprazole, asenapine, brexpiprazole, cariprazine, clozapine, haloperidol, iloperidone, lurasidone, olanzapine, paliperidone, pimavanserin, quetiapine, risperidone, ziprasidone
- *Gamma-Aminobutyric acid (GABA) analog anticonvulsants:* Gabapentin, pregabalin
- *Opioids:* Buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, oxymorphone, tapentadol, tramadol
- Anxiolytics
  a. *Benzodiazepines:* Alprazolam, clonazepam, diazepam, lorazepam, midazolam, oxazepam, temazepam
  b. *Serotonin-norepinephrine reuptake inhibitors (SNRIs)/Selective serotonin reuptake inhibitors (SSRIs):* Citalopram, desvenlafaxine, duloxetine, escitalopram, fluoxetine, fluvoxamine, levomilnacipran, milnacipran, paroxetine, sertraline, venlafaxine
  c. *Other:* Bupropion, buspirone, mirtazapine
- Combinations of any of the above

Combinations of Nonpharmacologic and Pharmacologic or Multimodal Interventions

Comparators

- KQ 1: Placebo, usual care, other non-pharmacological intervention or a combination of non-pharmacological interventions
- KQ 2: Placebo, usual care, other pharmacological intervention or dose or route, or a combination of pharmacological interventions
- KQ 3: Placebo, usual care, non-pharmacological interventions, pharmacologic interventions, or multimodal interventions (*e.g.,* opioids versus respiratory training, or acupuncture versus morphine versus combination acupuncture and morphine)
- KQ 4: Any of the comparators for KQ 1, KQ 2, or KQ 3

Outcomes

Patient- or Caregiver-Reported, or Observational Symptom-Related Outcomes (KQ1–3)

Caregiver-Reported or Observational Symptom-Related Only if Patients are Unable to Self-Report

- Dyspnea as measured by a validated tool, which must include *patient- or caregiver-reported or observational symptom-related measures* of breathing difficulty or discomfort
- Anxiety as measured by a validated tool. This tool must include *patient- or caregiver-reported* measures of anxiety
- Functional status (measured by validated *patient- or caregiver-reported tool*)
- Health-related quality of life (general or disease-specific, measured by a validated patient- or caregiver-reported tool)

Clinical or Utilization Health Outcomes (KQ1–4)

- Respiratory rate
- Oxygen or carbon dioxide/bicarbonate levels
- Heart rate
- Blood pressure
- Objective measure of functional capacity, *e.g.,* 6-minute walk test
- Level of sedation
- Utilization outcomes linked to dyspnea: hospitalizations, intensive care unit stays, emergency room visits

Patient-Centered Adverse Effects of Dyspnea Treatments (KQ4)

- Central nervous system (cognitive changes, dizziness, drowsiness, fatigue, headache, respiratory depression)
- Gastrointestinal (constipation, nausea, vomiting)
- Pruritus
- Urinary retention, dry mouth
- Opioid use disorder
- Discomfort or distress from equipment, *e.g.,* oxygen or masks
- Death
- Dropouts

Timing: Any Duration of Follow-up

Setting: Any Setting

Study Design: RCTs for all KQ

- For KQ1–3: RCTs, nonrandomized controlled trials, and observational studies with a concurrent comparison group, with at least 10 patients in each group
- For KQ 4: RCTs, nonrandomized controlled trials, observational studies with a concurrent comparison group, and prospective or retrospective cohort studies where the primary objective of the study is to evaluate harms from dyspnea treatments

Dated: October 28, 2019.

Virginia L. Mackay-Smith,

Associate Director, Office of the Director, AHRQ.

[FR Doc. 2019–23871 Filed 10–31–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0977]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

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 December 2, 2019.

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 0910–0312. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents—21 CFR 1140.30

OMB Control Number 0910–0312—Extension

This is a request for an extension of OMB approval for the information collection requirements contained in FDA's regulations for cigarettes and smokeless tobacco containing nicotine. The regulations that are codified at 21 CFR part 1140 are authorized by section 102 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31). Section 102 of the Tobacco Control Act required FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the regulation issued by FDA in 1996 (61 FR 44396, August 28, 1996), with certain specified exceptions including that subpart C (which included 21 CFR 897.24) and 21 CFR 897.32(c) be removed from the reissued rule (section 102(a)(2)(B)). The reissued final rule was published in the **Federal Register** of March 19, 2010 (75 FR 13225).

This collection includes reporting information requirements for § 1140.30 (21 CFR 1140.30), which directs persons to notify FDA if they intend to use a form of advertising that is not addressed in the regulations and not originally described in the March 19, 2010, final rule. Section 1140.30 requires manufacturers, distributors, and retailers to (1) observe certain format and content requirements for labeling and advertising and (2) notify FDA if they intend to use an advertising medium that is not listed in the regulations. The concept of permitted advertising in § 1140.30 is sufficiently broad to encompass most forms of advertising.

In the **Federal Register** of May 17, 2019 (84 FR 22496), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related. The commenter stated that this program is ineffective and has no effect on whether Americans smoke. FDA disagrees. Section 1140.30 is intended to help protect children and adolescents by reducing the appeal of cigarettes and smokeless tobacco to them. Section 1140.30, in part, contains a comprehensive list of permissible forms of advertising and labeling; in the unlikely event that a person wishes to use a form of advertising or labeling that is not described in § 1140.30, the section directs respondents to notify FDA of the form of advertising or labeling they intend to use.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1140.30—Scope of permissible forms of labeling and advertising	25	1	25	1	25

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

The burden hour estimates for this collection of information were based on industry-prepared data and information regarding cigarette and smokeless tobacco product advertising expenditures.

FDA estimates that approximately 25 respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice. Therefore, FDA estimates that the total time required for this collection of information is 25 hours.

We have adjusted our burden estimate to approximately 25 notifications annually, which more accurately reflects the current number of submissions under this regulation. This is a decrease to the currently approved burden. The decrease in notifications is not unexpected given that the regulation applies to cigarettes and smokeless tobacco and many of the alternative media notifications have been made in previous years.

Dated: October 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23934 Filed 10–31–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–P–2982]

Determination That MEXITIL (Mexiletine Hydrochloride) Capsules, 150 Milligrams, 200 Milligrams, and 250 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that MEXITIL (mexiletine hydrochloride) capsules, 150 milligrams (mg), 200 mg, and 250 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for MEXITIL (mexiletine hydrochloride) capsules, 150 mg, 200 mg, and 250 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carlarease Hunter, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3702, *Carlarease.Hunter@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an