



MRx CLINICAL ALERT

YOUR MONTHLY SOURCE FOR DRUG INFORMATION HIGHLIGHTS

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FDA UPDATES ON DRUG IMPURITIES

The United States (US) Food and Drug Administration (FDA) continues to investigate the presence of nitrosamine impurities in various medications. Outside the US, low levels of N-nitrosodimethylamine (NDMA), similar to amounts observed in certain foods and water, have recently been found in the diabetes medication metformin. As a result, some metformin products have been recalled in other countries. To date, no US metformin products have been recalled. The US FDA is assessing metformin to determine whether any samples contain NDMA, and if so, whether these levels are greater than the previously defined acceptable daily intake level of 96 ng/day or 0.32 ppm. If high levels are detected, the agency will inform the public and initiate product recalls. The FDA recommends that patients with type 2 diabetes mellitus (T2DM) who are managed with metformin continue therapy and that healthcare professionals (HCP) continue to prescribe metformin as indicated. Metformin is recommended as the preferred initial medication for T2DM management.

In addition, the FDA announced they are requesting manufacturers of the oral histamine-2 (H2) blockers ranitidine and nizatidine to test all product lots for NDMA. The FDA is requiring that manufacturers inform the agency if thresholds exceed the acceptable daily intake limit and withhold releasing affected lots. The FDA will also assess the link between the presence of

nitrites plus ranitidine or nizatidine in the body and the formation of NDMA. Currently, the FDA is instructing patients who are taking these medications to limit intake of foods containing nitrites, such as processed meats and those containing the preservative sodium nitrite. An alternative is to switch to a medication that has not been found to contain NDMA, such as another H2 blocker (e.g., cimetidine or famotidine) or a proton pump inhibitor (PPI).

2020 COPD GUIDELINES

The 2020 Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy for prevention, diagnosis, and management of chronic obstructive pulmonary disease (COPD) has been released. Overall guiding principles are unchanged from the 2019 update. The changes for 2020 include: (1) additional details on the use of eosinophils as an efficacy biomarker for inhaled corticosteroids (ICS), (2) further delineation of the role of non-drug therapies, and (3) refinement of the diagnosis of exacerbation with additional details on other potential diagnoses.

Key revisions include the addition of a new table around use of non-pharmacological treatments for COPD. Non-drug therapies include patient education on self-management and the role of pulmonary rehabilitation, influenza and pneumococcal vaccinations, nutritional supplementation, physical activity, and management of risks (smoking, environmental exposures). A second table was added with several differential diagnoses to consider before diagnosing

a COPD exacerbation; these include lung conditions, such as embolism, pneumonia, and edema, as well as cardiac arrhythmias. The addition of a new infographic outlines key factors to consider when starting ICS therapy in combination with 1 or 2 long-acting bronchodilators. There is strong support for starting an ICS in patients with a history of hospitalizations for COPD exacerbations or ≥ 2 moderate exacerbations per year, despite long-acting bronchodilator maintenance therapy; blood eosinophils > 300 cell/ μL ; and a history of or concurrent asthma. ICS initiation can be considered in patients with blood eosinophils of 100 to 300 cells/ μL and 1 moderate COPD exacerbation per year. For patients with repeated pneumonia events, blood eosinophils < 100 cell/ μL , or a history of mycobacterial infection, initiating ICS therapy is not recommended. Finally, the infographic on the COPD management cycle was expanded to include diagnosis, initial assessment, and initial management of COPD, as well as review of patient's clinical status and adjustment of therapy (pharmacologic and non-pharmacologic).

Other notable revisions to the guidelines include the addition of the anti-interleukin (IL)-5 agents benralizumab and mepolizumab as options with anti-inflammatory potential. In addition, recent data suggest that antibiotic usage can be restricted without negative health outcomes when the C-reactive protein (CRP) is low.

■ ICER REPORT ON JAK INHIBITORS

The Institute for Clinical and Economic Review (ICER) published an evidence report on the effectiveness and economic value of oral Janus kinase (JAK) inhibitors in adults with moderate to severe rheumatoid arthritis (RA). Evidence from studies comparing JAK inhibitors to conventional disease modifying antirheumatic drugs (cDMARDs), such as methotrexate (MTX), revealed significant improvements in disease measures for both upadacitinib and tofacitinib. ICER concluded with high certainty that upadacitinib and tofacitinib provide substantial net health benefit compared to cDMARDs; however, evidence is insufficient to compare baricitinib to the cDMARDs. Based on economic modeling, ICER found that upadacitinib provides marginal clinical benefit compared to adalimumab but at a higher cost. Nevertheless, cost-effectiveness estimates for upadacitinib fall under the cost-utility threshold of \$150,000 per quality-adjusted life year.

In the SELECT-COMPARE study, upadacitinib plus MTX was associated with a significant, though modest, increase in rates of disease remission, American College of Rheumatology (ACR) response, change in pain, and improvement in Health Assessment Questionnaire for Rheumatoid Arthritis Disability Index (HAQ-DI) compared to

adalimumab plus MTX. ICER determined that the evidence provides moderate certainty that, when combined with MTX, upadacitinib offers a better net health benefit compared to adalimumab. Two head-to-head trials comparing tofacitinib to adalimumab found no significant differences in clinical outcomes between the 2 agents; therefore, ICER concluded with high certainty that tofacitinib and adalimumab provide comparable net health benefit. There are no head-to-head data to compare baricitinib to adalimumab. Short-term (within 6 months) safety profiles of JAK inhibitors, adalimumab, and cDMARDs were comparable, and long-term (≥ 1 year) safety profiles were similar among the JAK inhibitors.



BEHAVIORAL HEALTH CORNER

FDA FRAMEWORK FOR GUIDANCE OF ACUTE OPIOID PRESCRIBING

The FDA commissioned the National Academies of Sciences, Engineering, and Medicine (NASEM) to create a framework in which to evaluate opioid prescribing for acute pain and to identify areas for further research. While appropriate access to opioids is crucial, the FDA encourages "right size" prescribing and a reduction in the number of people who are needlessly exposed to opioids. Based on their findings, the panel recommends that evidenced-based clinical practice guidelines (CPG) use an accepted method for grading the evidence and rating the strength of recommendations. CPGs should clearly specify use in specific areas, such as patient population and subpopulations, treatment setting, and prior treatment. The NASEM recommends that clinical trial data be specific to drug, dosage, and duration, and urges the use of morphine milligram equivalents (MME) when comparing efficacy of opioid agents. Stakeholders, such as professional societies, healthcare organizations, and insurers, should assess CPG impact on short- and long-term opioid prescribing practices. These include health outcomes, opioid misuse, and opioid-related overdoses and deaths. The panel prioritizes certain medical and surgical conditions that should be considered in CPGs for acute pain management. Researchers and developers of CPGs should outline appropriate use and optimal prescribing strategies, including opioid and nonpharmacologic alternatives, and assess their impact on opioid use in the setting of acute pain. Lastly, the panel recommends further research in key areas, such as population-based patient outcomes, impact of clinical setting on prescribing, and association of intermediate markers (e.g., unused medication, long-term opioid use) on health outcomes.

DRUG INFORMATION HIGHLIGHTS

- Flu Season Update (2019-2020): The Centers for Disease Control and Prevention (CDC) reported that the influenza like illnesses (ILI) activity in the US continued to rise during the week ending December 28, 2019. Nationwide, the influenza B/Victoria virus predominates, followed by A(H1N1)pdm09. The District of Columbia, New York City, Puerto Rico, and 34 states reported high ILI activity; 9 states reported moderate activity; and the remaining states reported low to minimal activity. At last report, 6.9% of patient visits were due to ILI, which is above the national baseline of 2.4%; although, lower routine healthcare visits during this holiday week may have skewed this number. No shortages of influenza antivirals to treat or prevent the flu have been reported.
- Since 2001, the proportion of individuals with human immunodeficiency virus (HIV) resistant to certain drugs has grown from 11% to 29%. The FDA recently approved a next generation sequencing (NGS) test, the Sentosa® SQ HIV Genotyping Assay, for the detection of HIV type-1 drug resistance mutations from patient's blood. This approval marks the first HIV drug resistance testing assay utilizing this NGS technology. The test can be used to identify virus mutations before or during antiviral treatment. The assay can detect 342 HIV drug-resistant mutations and is intended for use to help guide antiretroviral therapy.
- Glenmark issued a consumer-level voluntary recall of all unexpired lots of ranitidine 150 mg and 300 mg tablets due to the presence of NDMA above acceptable limits. The company will stop distribution of ranitidine products as it continues to investigate causes.
- Lannett is voluntarily recalling 2 lots of levetiracetam oral solution 100 mg/mL to the consumer level due to contamination with *Bacillus subtilis*. While there is potential for severe infection if used in immunocompromised patients, no adverse events have been reported related to affected lots of the anti-epileptic drug.
- The FDA reported that Jazz Pharmaceuticals will discontinue distribution of the atypical antipsychotic clozapine orally disintegrating tablet (ODT) (Fazacllo®) based on a commercial decision. Generic clozapine ODT remains commercially available.
- The International Consensus Group released new recommendations regarding the management of nonvariceal upper gastrointestinal bleeding (UGIB), as an update of their 2010 guidance. Although the annual incidence of acute UGIB has declined, the 30-day mortality rate is 11%. The recommendations address the endoscopic management as well as pharmacological management and secondary prophylaxis. Regarding pharmacological management, high risk patients with bleeding ulcers with successful endoscopic treatment should receive high-dose PPI therapy with an intravenous (IV) loading dose, followed by a continuous infusion for 3 days. It is suggested that an oral PPI then be given twice daily for 14 days, followed by once daily treatment, for a total duration dependent on the severity of the bleeding lesion. In terms of secondary prophylaxis, PPI therapy is suggested for patients with previous ulcer bleeding who are receiving antiplatelet or anticoagulant therapy.

PIPELINE NEWS: UPCOMING PRESCRIPTION DRUG/BIOSIMILAR USER FEE ACT (PDUFA/BsUFA) DATES

- **January 2020:** pembrolizumab (Keytruda®); IV programmed cell death 1 (PD-1) inhibitor; bladder cancer (monotherapy, BCG-unresponsive, high-risk, non-muscle invasive); Merck.
- **January 2020:** AR101; oral peanut protein; peanut allergy; Aimmune.
- **Jan-Mar 2020:** empagliflozin/linagliptin/metformin extended-release (ER); oral fixed-dose sodium-glucose co-transporter 2 (SGLT2) inhibitor/dipeptidyl peptidase-4 (DPP-4) inhibitor/biguanide; T2DM; Boehringer-Ingelheim.
- **Jan-Mar 2020:** osilodrostat; oral aldosterone synthase inhibitor; Cushing's syndrome; Recordati/Novartis.
- **January 20, 2020:** semaglutide (Ozempic®); SC glucagon-like peptide-1 (GLP-1) receptor agonist; cardiovascular (CV) risk reduction in patients with T2DM; Novo Nordisk.
- **January 20, 2020:** semaglutide (Rybelsus®); oral GLP-1 agonist; CV risk reduction in patients with T2DM; Novo Nordisk.
- **January 23, 2020:** tazemetostat; oral EZH2 inhibitor; Sarcoma; Royalty.
- **January 24, 2020:** fidaxomicin (Dificid®); oral macrolide antibiotic; *Clostridium difficile*-associated diarrhea (pediatrics); Merck.
- **January 28, 2020:** risperidone ER; intramuscular (IM) atypical antipsychotic; schizophrenia, bipolar disorder; Luye.
- **January 29, 2020:** leuprolide mesylate depot (ready-to-use); SC gonadotropin-releasing hormone agonist; prostate cancer; Foresee.

RECENT FDA APPROVALS

| DRUG NAME MANUFACTURER | DESCRIPTION |
|---|--|
| New Drugs | |
| givosiran (Givlaari™) Alnylam | <ul style="list-style-type: none"> • NDA approval 11/20/2019; Breakthrough Therapy, Orphan Drug, Priority Review • Indicated for acute hepatic porphyria • Aminolevulinate synthase 1 (ALAS1)-directed small interfering ribonucleic acid (siRNA) • Injection: 189 mg/mL single-dose vial (SDV) • Recommended dosage is 2.5 mg/kg administered SC once monthly by an HCP • Available medical support is recommended to manage anaphylactic reaction |
| cenobamate (Xcopri®) SK Life Science | <ul style="list-style-type: none"> • NDA approval 11/21/2019 • Indicated for the treatment of partial-onset seizures in adults • Voltage-gated sodium current inhibitor/GABA_A ion channel modulator • Tablets: 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg • Recommended initial dosage is 12.5 mg orally once daily, titrated up to 200 mg once daily; maximum daily dose is 400 mg • Product availability is expected in 2Q2020, following controlled substance scheduling |
| riluzole (Exservan™) Aquestive Therapeutics | <ul style="list-style-type: none"> • 505(b)(2) NDA approval 11/22/2019; Orphan Drug • Indicated for the treatment of amyotrophic lateral sclerosis (ALS) • Benzothiazole • Oral film: 50 mg • Recommended dosage is 50 mg orally twice daily, at least 1 hour before or 2 hours after a meal; should be taken without water • Aquestive Therapeutics is seeking a US commercial partner |
| voxelotor (Oxbryta™) Global Blood Therapeutics | <ul style="list-style-type: none"> • NDA approval 11/25/2019; Accelerated Approval, Breakthrough Therapy, Orphan Drug, Priority Review, Rare Pediatric Disease • Indicated for the treatment of sickle cell disease (SCD) in adults and pediatrics ages ≥ 12 years; continued approval may depend on confirmatory trials • Hemoglobin S polymerization inhibitor • Tablet: 500 mg • Recommended dosage is 1,500 mg orally once daily without regard to food • Available through the manufacturer's specialty pharmacy partner network |
| methotrexate (Reditrex™) Cumberland | <ul style="list-style-type: none"> • 505(b)(2) NDA approval 11/27/2019 • Indicated for: <ul style="list-style-type: none"> » the management of severe, active RA and polyarticular juvenile idiopathic arthritis (pJIA) in patients who are intolerant of or inadequately responsive to first-line therapy; » symptomatic control of severe, recalcitrant, disabling psoriasis (PSO) in adults who are inadequately responsive to other therapies • Folate analog metabolic inhibitor • Injection: 7.5 mg/0.3 mL, 10 mg/0.4 mL, 12.5 mg/0.5 mL, 15 mg/0.6 mL, 17.5 mg/0.7 mL, 20 mg/0.8 mL, 22.5 mg/0.9 mL, and 25 mg/mL strengths in single-dose, pre-filled syringes • Recommended initial dosage is listed below; adjust dose to achieve optimal response <ul style="list-style-type: none"> » RA: 7.5 mg SC once weekly » pJIA: 10 mg/m² SC once weekly » PSO: 10 mg to 25 mg SC once weekly • Patient or caregiver may administer with proper training on administration and handling • Boxed warnings for severe toxic reactions, including embryo-fetal toxicity and death |

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RECENT FDA APPROVALS *continued*

| DRUG NAME MANUFACTURER | DESCRIPTION |
|---|--|
| New Drugs <i>continued</i> | |
| <p>infliximab-axxq (Avsola™) Amgen</p> | <ul style="list-style-type: none"> • BLA approval 12/06/2019; biosimilar to Remicade® • Indicated for the management of adults with active ankylosing spondylitis (AS), active psoriatic arthritis (PsA), or chronic severe PSO, and adult and pediatric patients with moderately to severely active RA, Crohn’s disease (CD), or ulcerative colitis (UC) • Tumor necrosis factor (TNF) inhibitor • Injection: 100 mg lyophilized powder in a SDV • Recommended dosages are given IV over at least 2 hours <ul style="list-style-type: none"> » PSO, PsA, and UC: 5 mg/kg at weeks 0, 2, and 6, then every 8 weeks thereafter » CD: 5 mg/kg at weeks 0, 2, and 6, then every 8 weeks thereafter; may increase up to 10 mg/kg in adults » RA: 3 mg/kg at weeks 0, 2, and 6, then every 8 weeks thereafter; may increase up to 10 mg/kg every 4 weeks » AS: 5 mg/kg at weeks 0, 2, and 6, then every 6 weeks thereafter • Boxed warning for serious infections and malignancy |
| <p>golodirsen (Vyondys 53™) Sarepta</p> | <ul style="list-style-type: none"> • NDA approval 12/12/2019; Accelerated Approval, Orphan Drug, Priority Review • Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping; continued approval may depend on results of confirmatory trials • Antisense oligonucleotide • Injection: 100 mg/2 mL SDV • Recommended dosage is 30 mg/kg administered once weekly IV over 35 to 60 minutes |
| <p>enfortumab vedotin-ejfv (Padcev™) Astellas</p> | <ul style="list-style-type: none"> • BLA approval 12/18/2019 • Indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1 or programmed death-ligand 1 (PD-L1) inhibitor, and platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting • Nectin-4-directed antibody and microtubule inhibitor conjugate • Injection: lyophilized powder in 20 mg and 30 mg SDVs • Recommended dosage is 1.25 mg/kg (not to exceed 125 mg) administered by an HCP IV over 30 minutes on days 1, 8, and 15 of a 28-day cycle until disease progression or unacceptable toxicity |
| <p>tazarotene (Arazlo™) Bausch Health</p> | <ul style="list-style-type: none"> • 505(b)(2) NDA approval 12/18/2019 • Indicated for the topical treatment of acne vulgaris in patients ages ≥ 9 years • Retinoid • Lotion: 0.045% • Apply a thin layer to affected areas once daily • Product availability is expected in the first half of 2020 |
| <p>ebola zaire vaccine, live (Ervebo®) Merck</p> | <ul style="list-style-type: none"> • BLA approval 12/19/2019; Breakthrough Therapy, Priority Review • Indicated for the prevention of disease caused by <i>Zaire ebolavirus</i> in individuals ages ≥ 18 years; does not protect against other species of <i>Ebolavirus</i> or <i>Marburgvirus</i>; duration of protection is unknown • Injection: 1 mL suspension in a SDV • Recommended dosage is a single 1 mL IM injection • Product availability is expected in 3Q2020 |

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RECENT FDA APPROVALS *continued*

| DRUG NAME MANUFACTURER | DESCRIPTION |
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| New Drugs <i>continued</i> | |
| levamlodipine maletate (Conjupri®) CSPC Ouyi | <ul style="list-style-type: none"> • 505(b)(2) NDA approval 12/19/2019 • Indicated as monotherapy or in combination with other antihypertensive agents for the treatment of hypertension, to lower blood pressure • Calcium channel blocker • Tablets: 1.25 mg, 2.5 mg, and 5 mg • Recommended initial dosage in adults is 2.5 mg once daily with a maximum dose of 5 mg once daily; initial dosage in small, fragile, or elderly adults is 1.25 mg once daily; initial dosage in pediatrics is 1.25 mg to 2.5 mg once daily (dosages > 2.5 mg in pediatrics have not been studied) |
| fam-trastuzumab deruxtecan-nxki (Enhertu®) Daiichi Sankyo/ AstraZeneca | <ul style="list-style-type: none"> • BLA approval 12/20/2019; Accelerated Approval, Breakthrough Therapy • Indicated for the treatment of adults with unresectable or metastatic HER2-positive breast cancer who have received ≥ 2 prior anti-HER2-based regimens in the metastatic setting; continued approval may depend on confirmatory trial results • HER2-directed antibody and topoisomerase inhibitor conjugate • Injection: 100 mg lyophilized powder in a SDV • Recommended dosage is 5.4 mg/kg given as IV infusion once every 21 days until disease progression or unacceptable toxicity; administer initial dose over 90 minutes, if tolerated give subsequent doses over 30 minutes • Do not substitute for or with trastuzumab (Herceptin®) or ado-trastuzumab (Kadcyla®) • Boxed warnings for interstitial lung disease and embryo-fetal toxicity |
| lembroxant (Dayvigo™) Eisai | <ul style="list-style-type: none"> • NDA approval 12/20/2019 • Indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance • Orexin receptor antagonist • Tablets: 5 mg and 10 mg • Recommended dosage is 5 mg orally taken no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening; maximum dosage is 10 mg once daily; administration with or soon after a meal may delay sleep onset • Product availability will follow Drug Enforcement Administration (DEA) scheduling, which is expected to occur within 90 days of FDA approval |
| ubrogepant (Ubrelvy™) Allergan | <ul style="list-style-type: none"> • NDA approval 12/23/2019 • Indicated for the acute treatment of migraine with or without aura in adults • Calcitonin gene-related peptide receptor antagonist • Tablets: 50 mg and 100 mg • Recommended dosage is 50 mg or 100 mg orally as needed; may administer a second dose at least 2 hours after the initial dose; do not exceed 200 mg in a 24-hour period • Product availability is expected in 1Q2020 |
| lumateperone (Caplyta®) Intra-Cellular Therapies | <ul style="list-style-type: none"> • NDA approval 12/23/2019 • Indicated for the treatment of schizophrenia in adults • Atypical antipsychotic • Capsule: 42 mg • Recommended dosage is 42 mg once daily with food; no dose titration is required • Boxed warning for increased mortality in elderly patients with dementia-related psychosis • Product availability is expected in late 1Q2020 |

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RECENT FDA APPROVALS *continued*

| DRUG NAME MANUFACTURER | DESCRIPTION |
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| Expanded Indications | |
| acalabrutinib (Calquence®) AstraZeneca | <ul style="list-style-type: none"> • sNDA approval 11/21/2019 • New indication for the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) • Recommended dosing is 100 mg orally every 12 hours |
| insulin glargine (Toujeo®) Sanofi | <ul style="list-style-type: none"> • sNDA approval 11/26/2019 • Expanded indication to include pediatrics 6 to 17 years old with diabetes mellitus (types 1 and 2) • Recommended SC dosage is individualized based on type of diabetes, metabolic needs, blood glucose monitoring results, and glycemic control goal |
| atezolizumab (Tecentriq®) Genentech | <ul style="list-style-type: none"> • sBLA approval 12/03/2019 • New indication for first-line treatment of adults with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations, in combination with paclitaxel protein-bound and carboplatin • Recommended dosage is 1,200 mg IV every 3 weeks until disease progression or unacceptable toxicity |
| tofacitinib ER (Xeljanz® XR) Pfizer | <ul style="list-style-type: none"> • sNDA 12/12/2019 • New indication for the treatment of adults with moderately to severely active UC who have had an inadequate response or who are intolerant to TNF blockers; tofacitinib immediate-release (Xeljanz®) was approved for this indication in May 2018 • Recommended induction dosage is 22 mg orally once daily for 8 to 16 weeks; maintenance dosage is 11 mg once daily |
| icosapent ethyl (Vascepa®) Amarin | <ul style="list-style-type: none"> • sNDA 12/13/2019 • New indication as adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adults with elevated triglycerides (≥ 150 mg/dL) and established cardiovascular disease (CVD) or diabetes mellitus and ≥ 2 additional CVD risk factors • Recommended dosage is 2 g twice daily taken orally with food |
| enzalutamide (Xtandi®) Astellas | <ul style="list-style-type: none"> • sNDA 12/16/2019 • New indication for the treatment of metastatic castration-sensitive prostate cancer; previously approved for castration-resistant prostate cancer • Recommended dosage is 160 mg (four 40 mg capsules) orally once daily |

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References:

annals.org cdc.gov fda.gov goldcopd.org icer-review.org