Wireless Telecommunications Bureau and Wireline Competition Bureau (the Bureaus) may implement, and (3) certify its challenge. The USAC system will validate a challenger's evidence using an automated challenge validation process. Once all valid challenges have been identified, a challenged party that chooses to respond to any valid challenge(s) may submit additional data via the online USAC portal during the established response window. A challenged party may submit technical information that is probative regarding the validity of a challenger's speed tests, including speed test data and other device-specific data collected from transmitter monitoring software or, alternatively, may submit its own speed test data that conforms to the same standards and requirements specified by the Commission and the Bureaus for challengers.

In conjunction with the qualified 4G LTE data separately collected pursuant to OMB 3060–1242 that will be used to create the map of areas presumptively eligible for MF–II support, the information collected under this MF–II challenge process collection will enable the Commission to efficiently resolve disputes concerning the eligibility or ineligibility of an area initially deemed ineligible for MF–II support and establish the final map of areas eligible for such support, thereby furthering the Commission's goal of targeting MF–II support to areas that lack adequate mobile voice and broadband coverage absent subsidies through a transparent process.

The Commission received approval from OMB for the information collection requirements contained in OMB 3060–1251 on February 7, 2018.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018–03000 Filed 2–13–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Thursday, February 15, 2018 at 10:00 a.m.

PLACE: 999 E Street NW, Washington, DC (Ninth Floor).

STATUS: This Meeting, open to the public, has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Signed:

Dayna C. Brown,

Secretary and Clerk of the Commission.

[FR Doc. 2018–03166 Filed 2–12–18; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than March 7, 2018.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Director of Applications) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Brandt J. Dufrene, Sr., individually and as trustee for The FSC Trust No. 1, and Brandt J. Dufrene, Jr., individually and as the trustee for The FSC Trust No. 2 and the Brandt J. Dufrene, Jr. Trust No. 1, all of Metairie, Louisiana;* to retain voting shares of First St. Charles Bancshares, Inc., and thereby indirectly retain First National Bank USA, both Boutte, Louisiana.

Board of Governors of the Federal Reserve System, February 9, 2018.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2018–03082 Filed 2–13–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[CDC–2018–0004; NIOSH–233–B]

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings: Proposed Additions to the NIOSH Hazardous Drug List 2018

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of draft document available for public comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability for public comment on the drugs proposed for placement on the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2018* (List), as well as the NIOSH *Policy and Procedures for Developing the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.*

DATES: Comments must be received by April 16, 2018.

ADDRESSES: Comments may be submitted, identified by docket numbers CDC–2018–0004 and NIOSH–233–B, by either of the following two methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34, 1090 Tusculum Avenue, Cincinnati, OH 45226–1998.

Instructions: All information received in response to this notice must include the agency name and the docket numbers (CDC–2018–0004; NIOSH–233–B). All relevant comments received will be posted without change to *www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Barbara MacKenzie, NIOSH, Robert A. Taft Laboratories, 1090 Tusculum Avenue, MS–C26, Cincinnati, OH 45226, telephone (513) 533–8132 (not a toll free number), Email: *hazardousdrugs@cdc.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested parties are invited to participate in this action by submitting written views, opinions, recommendation, and/or data. Comments are invited on any topic related to the drugs identified in this notice, including those evaluated for

placement on the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2018.* NIOSH also seeks comment on the draft *Policy and Procedures for Developing the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings,* available in the docket for this action. NIOSH invites comments specifically on the following questions related to this action:

1. Has NIOSH appropriately identified and categorized the drugs considered for placement on the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2018*?

2. Is information available from FDA or other Federal agencies or in the published, peer-reviewed scientific literature about a specific drug or drugs identified in this notice that would justify the reconsideration of NIOSH's categorization decision?

3. Does the draft *Policy and Procedures for Developing the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings* include a methodology for reviewing toxicity information that is appropriate for this activity?

II. Background

In September 2004, NIOSH published *NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings* (Alert).[1] The 2004 Alert set out a general NIOSH policy for the identification of hazardous drugs and contained examples of U.S. Food and Drug Administration (FDA)-approved drugs that were deemed to be hazardous to workers in health care and other settings and may require special handling. This initial list of hazardous drugs was updated in 2010,[2] 2012,[3] 2014,[4] and 2016.[5] The latest publication, entitled *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016* (2016 Update), covered all new approved drugs and drugs with new warnings through December 2013.

III. Policy and Procedures for Developing the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings

The NIOSH Director has developed draft policy and procedures, entitled *Policy and Procedures for Developing the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings,* to formalize the methodology NIOSH uses to guide the addition of hazardous drugs to the List (*see https://www.cdc.gov/niosh/topics/hazdrug/default.html*). The draft document clarifies and details the purpose of the List, which is to assist employers in providing safe and healthful workplaces by offering a list of drugs that meet the NIOSH definition of a hazardous drug, and sets out the procedures used by NIOSH to identify such drugs. The draft policy and procedures will be finalized after consideration of comments to this docket and from peer reviewers.[6]

According to the draft hazardous drugs policy and procedures, NIOSH defines a hazardous drug as a drug that is:

1. Approved for use in humans [7] by the FDA; [8] and

2. Not otherwise regulated by the U.S. Nuclear Regulatory Commission; [9] and

3. Either:

a. Accompanied by prescribing information in the ''package insert'' [10] that includes special handling information to protect workers handling the drug; or

b. Exhibits one or more of the following types of toxicity in humans, animal models, or *in vitro* systems: Carcinogenicity; teratogenicity or other developmental toxicity; reproductive toxicity; organ toxicity at low doses; genotoxicity; or structure and toxicity profile that mimics existing drugs determined hazardous by exhibiting any one of the previous five toxicity types.

In accordance with the draft hazardous drugs policy and procedures, NIOSH uses FDA databases to identify new drug approvals and drugs with new safety warnings.

Information pertaining to each new drug and drugs with new safety warnings is screened to determine whether a specific drug is potentially hazardous. Potentially hazardous drugs are those for which the manufacturer has provided special handling information intended to protect workers, or for which available toxicity information suggests that a drug may exhibit one of the types of toxicity in the NIOSH definition of a hazardous drug. Drugs for which insufficient toxicity information is available and drugs for which the available information suggests no toxic effect or a toxic effect that does not meet the NIOSH definition of a hazardous drug are not proposed for placement on the List and are not further considered. Drugs for which special handling information is available are published on the NIOSH website and proposed for placement on the List; these drugs are not further evaluated.

Drugs for which the available information suggests that the drug exhibits one or more toxic effects that meet the NIOSH definition of a hazardous drug are further evaluated to determine whether the drug should be proposed for placement on the List. To conduct the evaluation of drugs for which information suggests a toxic effect, NIOSH may consult the following sources of information to determine whether each screened drug might exhibit at least one type of toxicity in the NIOSH definition of a hazardous drug:

a. Information in the drug package insert;

b. FDA information pertaining to new drug safety labeling changes; [11]

c. When available, relevant information about carcinogenicity from:

(1) The National Toxicology Program (NTP) within the U.S. Department of Health and Human Services; [12]

(2) U.S. Environmental Protection Agency (EPA); [13]

[1] *See https://www.cdc.gov/niosh/docs/2004-165/.*

[2] *See https://www.cdc.gov/niosh/docs/2010-167/.*

[3] *See https://www.cdc.gov/niosh/docs/2012-150/.*

[4] *See https://www.cdc.gov/niosh/docs/2014-138/default.html.*

[5] *See https://www.cdc.gov/niosh/docs/2016-161/default.html.*

[6] *See https://www.cdc.gov/niosh/topics/hazdrug/peer-review-plan.html* for the charge to peer reviewers.

[7] Although only drugs approved by the FDA for use in humans are included in the definition of a hazardous drug, some of those drugs may be used in veterinary settings for treatment of animals and may be a hazard for veterinary care workers.

[8] 21 U.S.C. 301 *et seq.*

[9] 10 CFR parts 19, 20, and 35. *See https://www.nrc.gov/materials/miau/med-use.html.*

[10] *See* Drug Advertising: A Glossary of Terms at *https://www.fda.gov/drugs/resourcesforyou/consumers/prescriptiondrugadvertising/ucm072025.htm.* ''Prescribing information is also called product information, product labeling, or the package insert (''the PI''). It is generally drafted by the drug company and approved by the FDA. This information travels with a drug as it moves from the company to the pharmacist. It includes the details and directions healthcare providers need to prescribe the drug properly. It is also the basis for how the drug company can advertise its drug. The prescribing information includes such details about the drug as: Its chemical description; how it works; how it interacts with other drugs, supplements, foods, and beverages; what condition(s) or disease(s) it treats; who should not use the drug; serious side effects, even if they occur rarely; commonly occurring side effects, even if they are not serious; effects on specific groups of patients, such as children, pregnant women, or older adults and how to use it in these populations.''

[11] *See https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/.*

[12] NTP (National Toxicology Program, DHHS) [2016]. 14th report on carcinogens. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. *See https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html.*

[13] EPA (Environmental Protection Agency). Integrated Risk Information System (IRIS) Assessments. *See https://cfpub.epa.gov/ncea/iris2/atoz.cfm.*

(3) World Health Organization's International Agency for Research on Cancer (IARC); [14] and

(4) NIOSH.[15]

d. When available, relevant information about reproductive toxicity, teratogenicity, or developmental toxicity from the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR), and from its successor, the Office of Health Assessment and Translation (OHAT);

e. When available, published, peer-reviewed scientific literature about the hazard potential of a particular drug for workers in a healthcare setting, including any relevant studies cited in the drug package insert; and

f. When available, toxicity information from Safety Data Sheets (SDSs) provided by the manufacturer.

Reviewing the available human, animal, and *in vitro* data from those sources, NIOSH uses criteria included in the hazardous drugs policy and procedures to determine whether the available evidence demonstrates or supports any of the types of toxicity in the NIOSH definition of a hazardous drug. NIOSH makes an initial determination about each drug and then requests review and comment from independent peer reviewers.

After consideration of the peer reviews, NIOSH sorts all screened and evaluated drugs into one of five categories:

- Category 1—Special handling information
- Category 2—Insufficient toxicity information available to meet the NIOSH definition of a hazardous drug
- Category 3—Available information shows no toxic effect or shows a toxic effect that does not meet the NIOSH definition of a hazardous drug
- Category 4—Available toxicity information demonstrates or supports a determination that the drug does not meet the NIOSH definition of a hazardous drug
- Category 5—Available toxicity information demonstrates or supports a determination that the drug meets the NIOSH definition of a hazardous drug

The categorized drugs are identified in a **Federal Register** notice available for public and stakeholder comment for 60 days.

After consideration of all public and stakeholder comments received, NIOSH makes a final determination about the disposition of all identified drugs and publishes a notice in the **Federal Register** announcing publication of the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2018* on the NIOSH website.

IV. Identifying Potentially Hazardous Drugs

Consistent with the hazardous drugs policy and procedures described above, NIOSH consulted two FDA databases on a monthly basis since the 2016 Update to identify newly-approved drugs and biologics [16] and already-approved drugs for which the manufacturer has issued a new safety warning.[17] Through the monthly FDA database search, conducted from January 2014 through December 2015, NIOSH identified 74 new drugs that had received FDA approval and 199 drugs with new safety warnings. In addition to the drugs identified by the FDA database searches, the NIOSH Director received a request to evaluate two drugs, dihydroergotamine and isotretinoin, for placement on the List by an interested party. In sum, 275 drugs were identified between January 2014 and December 2015 and screened.

V. Screening of Potentially Hazardous Drugs

Upon identification by NIOSH, each drug was screened to determine whether the manufacturer specified special handling information in the package insert or if information in the package insert suggests that a drug may exhibit at least one of the types of toxicity in the NIOSH definition of a hazardous drug. For 18 drugs, existing toxicity information did not support placement on the List (*see* Table 1) and for 211 drugs and combination drugs, the available information suggests no toxic effect or a toxic effect that does not meet the NIOSH definition of a hazardous drug (*see* Table 2); those drugs are not proposed for placement on the List.

TABLE 1—INSUFFICIENT TOXICITY INFORMATION AVAILABLE TO MEET NIOSH DEFINITION OF HAZARDOUS DRUG

[Category 2]

Belimumab	Dinutuximab	Protriptyline
Betamethasone	Elosulfase	Sebelipase alfa
Cholic acid	Mepolizumab	Secukinumab
Daratumumab	Obinutuzumab	Siltuximab
Desipramine	Omalizumab	Vedolizumab
Dexamethasone	Pegaspargase	Velaglucerase

TABLE 2—AVAILABLE INFORMATION SHOWS A TOXIC EFFECT THAT DOES NOT MEET THE NIOSH DEFINITION OF HAZARDOUS DRUG

[Category 3]

Abatacept	Desvenlafaxine	Ketoconazole	Rasagiline
Aclidinium	Dexlansoprazole	Lamivudine	Regadenosone
Adalimumab	Diclofenac	Lansoprazole	Rifaximin
Adenosine	Diltiazem	Ledipasvir/Sofosbuvir	Rilpivirine
Aflibercept	Dimethyl fumarate	Lesinurad	Risedronate
Albiglutide	Dolasetron	Levetiracetam	Rivaroxaban
Alcaftadine	Doripenem	Levomilnacipran	Rivastigmine
Alirocumab	Doxazosin	Linaclotide	Rocuronium
Almotriptan	Doxepin	Linagliptin	Rolapitant
Anagrelide	Doxycycline	Lincomycin	Ropinirole
Apixaban	Droxidopa	Lisinopril	Rufinamide

[14] IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Lyon, France. *See http://monographs.iarc.fr/ENG/Classification/index.php.*

[15] NIOSH Carcinogen List. *See https://www.cdc.gov/niosh/topics/cancer/npotocca.html.*

[16] *Drugs@FDA: FDA Approved Drug Products. https://www.accessdata.fda.gov/scripts/cder/daf/.*

[17] *Drug Safety Labeling Changes. https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/.*

TABLE 2—AVAILABLE INFORMATION SHOWS A TOXIC EFFECT THAT DOES NOT MEET THE NIOSH DEFINITION OF HAZARDOUS DRUG—Continued

[Category 3]

Aripiprazole	Dulaglutide	Losartan	Ruxolitinib
Asenapine	Duloxetine	Lovastatin	Sacubitril/Valsartan
Asparaginase erwinia	Edoxaban	Lumacaftor/Ivacaftor	Sapropterin
Avanafil	Efavirenz	Maraviroc	Saquinavir
Baclofen	Efinaconazole	Methadone	Saxagliptin
Beclomethasone	Eliglustat	Methoxy polyethylene glycol-epoetin beta	Selegiline
Bedaquiline	Eltrombopag	Methylphenidate	Selexipag
Benazepril	Eluxadoline	Methylprednisolone	Sertraline
Bimatoprost	Empagliflozin	Minocycline	Sildenafil
Boceprevir	Escitalopram	Mirabegron	Simeprevir
Brexpiprazole	Esomeprazole	Mirtazapine	Simvastatin
Bupivacaine	Etidronate	Morphine	Sitagliptin
Buprenorphine	Evolocumab	Moxifloxacin	Sofosbuvir
Bupropion	Ezopiclone	Naloxegol	Somatropin
Calcitonin	Fentanyl	Natalizumab	Sugammadex
Canagliflozin	Ferumoxytol	Necitumumab	Sulfasalazine
Canakinumab	Filgrastim	Netupitant/Palonosetron	Sulfur hexafluoride lipid type-A
Cangrelor	Flibanserin	Nivolumab	Suvorexant
Captopril	Fluoxetine	Nortriptyline	Tadalafil
Carbidopa	Fluvoxamine	Olanzapine	Taligucerase
Cariprazine	Fondaparinux	Olodaterol	Tamsulosin
Cefepime	Gabapentin	Omeprazole	Tapentadol
Cefoperazone	Galantamine	Ondasetron	Tavaborole
Ceftazidime/Avibactam	Gemfibrozil	Oritavancin	Tedizolide
Ceftriaxone	Granisetron	Oxybutynin	Telithromycin
Cinacalcet	Hydrocodone	Oxycodone	Telmisartan
Citalopram	Hydrocortisone	Oxymorphone	Ticagrelor
Clindamycin	Hydromorphone	Palbociclib	Tolvaptan
Clomipramine	Ibandronate	Palonosetron	Trazodone
Clozapine	Ibrutinib	Panitumumab	Triamcinolone
Collagenase clostridium histolytica	Imipramine	Pantoprazole	Trimipramine
Dabigatran	Infliximab	Paricalcitol	Trypan blue
Daclatasvir	Ingenol	Pegfilgrastim	Uridine
Dalbavancin	Insulin degludec	Peginterferon alpha-2A	Vardenafil
Dalteparin	Insulin glargine	Peginterferon alpha-2B	Varenicline
Dapagliflozin	Insulin glulisine	Pembrolizumab	Venlafaxine
Dapsone	Interferon alfa-2b	Peramivir	Vigabatrin
Daptomycin	Interferon beta-1a	Pramlintide	Vilazodone
Darunavir	Interferon gamma-1b	Prazosin	Vorapaxar
Deferasirox	Ipilimumab	Rabeprazole	Vortioxetine
Denosumab	Ivacaftor	Ramipril	Zolpidem
Deoxycholic acid	Ivermectin	Ramucirumab	

Finally, the information available for 44 drugs suggests one or more toxic effects; those drugs were evaluated by NIOSH, as discussed below, and were shared with peer reviewers and stakeholders.[18]

VI. Evaluation of Potentially Hazardous Drugs

Consistent with the draft hazardous drugs policy and procedures, NIOSH evaluated the 44 drugs identified as potentially hazardous to determine whether each meets the NIOSH definition of a hazardous drug by exhibiting one or more of the following types of toxicity in humans, animal models, or *in vitro* systems: Carcinogenicity; teratogenicity or other developmental toxicity; reproductive toxicity; organ toxicity at low doses; genotoxicity; and/or a structure and toxicity profile of an isomer or close chemical analog of a drug on the List. Using criteria articulated in the draft hazardous drugs policy and procedures,[19] NIOSH reviewed the available information and sought to determine whether the evidence for each drug either demonstrates or supports a determination of toxicity. Initial determinations were made about each evaluated drug and then the list of evaluated drugs was given to peer reviewers and stakeholders for additional evaluation.

VII. Peer and Stakeholder Review of Potentially Hazardous Drugs

NIOSH conducted peer and stakeholder review of all evaluated drugs.[20] Four independent peer reviewers and eight stakeholders reviewed and commented on the 44 drugs. De-identified peer and stakeholder reviews will be placed in the docket for this action.

VIII. Evaluated Drugs That Do Not Meet the NIOSH Definition of a Hazardous Drug

After consideration of the peer and stakeholder reviews, NIOSH determined that the available toxicity information for 23 drugs does not meet the NIOSH definition of a hazardous drug (Category

[18] Historically, NIOSH has conducted peer review and stakeholder review concurrently, prior to publication of the list of drugs proposed for addition to the List. Beginning with the 2020 Update, NIOSH will conduct peer review prior to publication of the list of drugs proposed for addition, and will conduct public comment and stakeholder review concurrently.

[19] *See* section VII.C.

[20] *See https://www.cdc.gov/niosh/review/peer/isi/hazdrug2018-pr.html* for the charge to peer reviewers.

4). These drugs are not proposed for placement on the List and are identified in Table 3.

TABLE 3—AVAILABLE TOXICITY INFORMATION DOES NOT DEMONSTRATE OR SUPPORT A DETERMINATION THAT THE DRUG MEETS THE NIOSH DEFINITION OF A HAZARDOUS DRUG

[Category 4]

Aglucosidase	Diazoxide	Lanreotide
Alectinib	Elotuzumab	Metreleptin
Alendronate	Finafloxacin	Milnacipran
Alogliptin	Golimumab	Nintedanib
Apremilast	Idelalisib	Peginterferon beta-1A
Calcipotriene	Isavuconazonium	Pirfenidone
Cetuximab	Itraconazole	Tasimelteon
Clarithromycin	Lamotrigine	

IX. Drugs Proposed for Placement on the NIOSH List of Hazardous Drugs

NIOSH determined that the available toxicity information for 20 drugs and one class of drug demonstrates or supports a NIOSH determination that they meet the NIOSH definition of a hazardous drug are proposed for placement on the List (Category 5). These drugs are proposed for placement on the list and are identified in Table 4.

Two additional drugs have special handling information specified by the manufacturer and are proposed for placement on the List (*see* Table 4).[21]

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[21] The manufacturers of trabectedin and inotuzumab ozogamicin added special handling information to the package inserts after publication of the 2016 Update. Although these drugs have been categorized by NIOSH as ''hazardous'' since April 10, 2017, they will be formally added to the 2018 Update unless compelling evidence in support of not placing them on the List is offered by public commenters. *See https://www.cdc.gov/niosh/docs/2016-161/default.html.*

Table 4. Drugs Proposed for Placement on the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings* (Category 1 -- Special Handling Information & Category 5 -- Drug Meets the NIOSH Definition of Hazardous Drug)

Generic Drug Name		
Bevacizumab	**Formulation**[a] ..... IV **Dosage** ..... 5-15 mg/kg **AHFS Class**[b] ..... Antineoplastic **New Drug**[c] ..... Yes **Special Handling Information**[d] ..... No **2018 Update Table No.**[e] 1	**Rationale for Proposing Placement on the List** *Reproductive toxicity and Teratogenicity or other developmental toxicity*: ovarian failure in patients in clinical trials, embryo-fetal toxicity in rabbits **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=939b5d1f-9fb2-4499-80ef-0607aa6b114e
Blinatumomab	**Formulation** ..... IV **Dosage** ..... 9 mcg/day **AHFS Class** ..... Antineoplastic **New Drug** ..... Yes **Special Handling Information** ..... No **2018 Update Table No.** 1	**Rationale for Proposing Placement on the List** *Organ toxicity at low doses*: neurotoxicity at low doses in patients in clinical studies **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=38b482a8-960b-4591-9857-5031ecb830aa
Botulinum toxins, all forms including AbobotulinimtoxinA and OnabotulinumtoxinA	**Formulation** ..... IM **Dosage** ..... 1-1000 units **AHFS Class** ..... Neurotoxin **New Drug** ..... No **Special Handling Information** ..... No **2018 Update Table No.** 2	**Rationale for Proposing Placement on the List** *Organ toxicity at low doses and Teratogenicity or other developmental toxicity*: spread of toxin effects, reductions in fetal body weight and decreased fetal skeletal ossification at human dose **Package Insert** https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=botulinum+toxin+type+A&pagesize=200&page=1*
Ceritinib	**Formulation** ..... Capsule **Dosage** ..... 750 mg **AHFS Class** ..... Antineoplastic **New Drug** ..... Yes **Special Handling Information** ..... No **2018 Update Table No.** 1	**Rationale for Proposing Placement on the List** *Teratogenicity or other developmental toxicity*: embryo-fetal toxicity at low doses in rats and rabbits **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=fff5d805-4ffd-4e8e-8e63-6f129697563e
Clobazam	**Formulation** ..... Tablet, oral suspension **Dosage** ..... 20 mg/kg **AHFS Class** ..... Antiepileptic **New Drug** ..... No	**Rationale for Proposing Placement on the List** *Reproductive toxicity and Teratogenicity or other developmental toxicity*: embryo-fetal mortality and other harm at low doses in rats and rabbits, present in human breast milk

	Special Handling Information.....No **2018 Update Table No.**.....3	**Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=de03bd69-2dca-459c-93b4-541fd3e9571c
Cobimetinib	**Formulation**.....Tablet **Dosage**.....60 mg **AHFS Class**.....Antineoplastic **New Drug**.....Yes **Special Handling Information**.....No **2018 Update Table No.**.....1	**Rationale for Proposing Placement on the List** *Reproductive toxicity and Teratogenicity or other developmental toxicity*: increased post-implantation loss, including total litter loss in rats at low doses; post-implantation loss and fetal malformations in humans **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=c387579e-cee0-4334-bd1e-73f93ac1bde6
Darbepoetin alfa	**Formulation**.....IV, SQ **Dosage**.....0.45-2.25 mcg/kg **AHFS Class**.....Erythropoiesis stimulator **New Drug**.....No **Special Handling Information**.....No **2018 Update Table No.**.....2	**Rationale for Proposing Placement on the List** *Carcinogenicity*: progression or recurrence of several cancers in studies of patients with cancer; reduced body weight in offspring at low doses in rats and rabbits **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=0fd36cb9-c4f6-4167-93c9-8530865db3f9
Dihydroergotamine	**Formulation**.....IV, IM, SQ, nasal spray **Dosage**.....1 mg **AHFS Class**.....5HT receptor binder **New Drug**.....No **Special Handling Information**.....No **2018 Update Table No.**.....3	**Rationale for Proposing Placement on the List** *Reproductive toxicity*: oxytocic properties at low doses in humans **Package Insert** https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Dihydroergotamine *
Exenatide	**Formulation**.....SQ **Dosage**.....2 mg/week **AHFS Class**.....Antidiabetic **New Drug**.....No **Special Handling Information**.....No **2018 Update Table No.**.....2	**Rationale for Proposing Placement on the List** *Carcinogenicity and Teratogenicity or other developmental toxicity*: thyroid C-cell tumors in rat studies; adverse fetal effects in rats and mice **Package Insert** https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Exenatide *
Inotuzumab ozogamicin	**Formulation**.....IV **Dosage**.....0.5-0.8 mg/m^2 **AHFS Class**.....Antineoplastic **New Drug**.....Yes **Special Handling Information**.....Yes	**Rationale for Proposing Placement on the List** *Manufacturer special handling information*: drug is cytotoxic, users should follow applicable OSHA handling and disposal procedures **Package Insert**

	2018 Update Table No......1	https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=cc7014b1-c775-411d-b374-8113248b4077
Interferon beta-1b	**Formulation**.....SQ **Dosage**.....0.25 mg **AHFS Class**.....Immune modulator **New Drug**.....No **Special Handling Information**.....No **2018 Update Table No.**.....2	**Rationale for Proposing Placement on the List** *Reproductive toxicity*: spontaneous abortions in human clinical trials **Package Insert** https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Interferon+beta-1b
Isotretinoin	**Formulation**.....Capsule **Dosage**.....0.5-1 mg/kg **AHFS Class**.....Retinoid **New Drug**.....No **Special Handling Information**.....No **2018 Update Table No.**.....3	**Rationale for Proposing Placement on the List** *Teratogenicity or other developmental toxicity*: severe fetal malformations at any dose in humans **Package Insert** https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Isotretinoin *
Ivabradine	**Formulation**.....Tablet **Dosage**.....5-7.5 mg **AHFS Class**.....HCN blocker **New Drug**.....Yes **Special Handling Information**.....No **2018 Update Table No.**.....3	**Rationale for Proposing Placement on the List** *Teratogenicity or other developmental toxicity*: embryo-fetal toxicity and teratogenicity at low doses in rats **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=92018a65-38f6-45f7-91d4-a34921b81d0d
Lenvatinib	**Formulation**.....Capsule **Dosage**.....24 mg **AHFS Class**.....Antineoplastic **New Drug**.....Yes **Special Handling Information**.....No **2018 Update Table No.**.....1	**Rationale for Proposing Placement on the List** *Teratogenicity or other developmental toxicity*: embryo-fetal toxicity at low doses in rats and rabbits; abortifacient in rabbits at low doses **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f4bedd21-efde-44c6-9d9c-b48b78d7ed1e
Miltefosine	**Formulation**.....Capsule **Dosage**.....50 mg **AHFS Class**.....Antibiotic **New Drug**.....Yes **Special Handling Information**.....No **2018 Update Table No.**.....3	**Rationale for Proposing Placement on the List** *Teratogenicity or other developmental toxicity*: fetal death and teratogenicity at low doses in rats and rabbits **Package Insert** https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Miltefosine *
Olaparib	**Formulation**.....Capsule	**Rationale for Proposing Placement on the List**

	Dosage.....400 mg **AHFS Class**.....Antineoplastic **New Drug**.....Yes **Special Handling Information**.....No **2018 Update Table No.**.....1	*Carcinogenicity and Teratogenicity or other developmental toxicity*: myelodysplastic syndrome/acute myeloid leukemia in patients in clinical studies; embryo-fetal toxicity, post implantation loss, malformations at low doses in rats **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e31a6a9-864f-4aba-8085-37ee1ddcd499
Osimertinib	**Formulation**.....Tablet **Dosage**.....80 mg **AHFS Class**.....Antineoplastic **New Drug**.....Yes **Special Handling Information**.....No **2018 Update Table No.**.....1	**Rationale for Proposing Placement on the List** *Teratogenicity or other developmental toxicity*: embryo-fetal toxicity and lethality and reduced growth in offspring in rats **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=5e81b4a7-b971-45e1-9c31-29cea8c87ce7
Sonidegib	**Formulation**.....Capsule **Dosage**.....200 mg **AHFS Class**.....Antineoplastic **New Drug**.....Yes **Special Handling Information**.....No **2018 Update Table No.**.....1	**Rationale for Proposing Placement on the List** *Reproductive toxicity and Teratogenicity or other developmental toxicity*: embryo-fetal toxicity, teratogenesis, and spontaneous abortions at low doses in rabbits **Package Insert** https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=Sonidegib *
Trabectedin	**Formulation**.....IV **Dosage**.....1.5 mg/m^2 **AHFS Class**.....Antineoplastic **New Drug**.....Yes **Special Handling Information**.....Yes **2018 Update Table No.**.....1	**Rationale for Proposing Placement on the List** *Manufacturer special handling information*: drug is cytotoxic, users should follow applicable OSHA handling and disposal procedures **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=472bd78e-be17-4b9d-90f4-9482c3aec9ff
Trastuzumab	**Formulation**.....IV **Dosage**.....2-6 mg/kg **AHFS Class**.....Antineoplastic **New Drug**.....No **Special Handling Information**.....No **2018 Update Table No.**.....1	**Rationale for Proposing Placement on the List** *Organ toxicity at low doses and Teratogenicity or other developmental toxicity*: cardiac and pulmonary toxicity in patients; malformations and neonatal death in patients **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=492bddb2-077e-4064-bff3-372d6af0a7a2
Triazolam	**Formulation**.....Tablet	**Rationale for Proposing Placement on the List**

	Dosage.....0.25 mg **AHFS Class**.....Hypnotic **New Drug**.....No **Special Handling Information**.....No **2018 Update Table No.**.....3	*Mimics existing drugs determined hazardous by exhibiting teratogenicity or other developmental toxicity*: drug is a benzodiazepine, a class known to cause congenital malformations and cross placenta in patients **Package Insert** https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=all&query=triazolam&pagesize=200&page=1
Urofollitropin	**Formulation**.....IM, SQ **Dosage**.....150-450 IU **AHFS Class**.....Ovulation stimulator **New Drug**.....No **Special Handling Information**.....No **2018 Update Table No.**.....3	**Rationale for Proposing Placement on the List** *Teratogenicity or other developmental toxicity*: drug is known to cause fetal harm in patients **Package Insert** https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9bb87daf-d156-504e-adaf-4c21383f8d16

[a] IM = intramuscular, IV = intravenous, SQ = subcutaneous
[b] AHFS (American Hospital Formulary Service) Pharmacologic-Therapeutic Classification system.
[c] FDA-approved drug (January 2014-December 2015).
[d] Manufacturer's package insert statement cautioning that the drug should be handled as hazardous.
[e] The final *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings* is subdivided into three tables: Table 1 contains antineoplastic drugs, including those with special handling information provided by the manufacturer; Table 2 contains non-antineoplastic drugs, including those with special handling information; and Table 3 contains non-antineoplastic drugs that primarily have adverse reproductive and/or teratogenic effects.
* Individual package inserts from multiple manufacturers were reviewed.

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X. Drugs Removed From the NIOSH List of Hazardous Drugs

In a petition to NIOSH in February 2017, the pharmaceutical company Theravance Biopharma requested the removal of the drug telavancin from the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.*[22] The petition included an analysis of animal developmental toxicity studies and argued that ''[p]lacing telavancin in the NIOSH category of a hazardous drug greatly overstates the occupational risk to healthcare workers handling telavancin.'' In response, NIOSH evaluated the information provided in the petition as well as other sources provided to NIOSH by the manufacturer and determined that telavancin does not meet the NIOSH definition of a hazardous drug. NIOSH informed users of the 2016 List of this determination via a web posting and responded to Theravance Biopharma with a letter dated April 12, 2017.[23] Accordingly, telavancin does not appear in the 2018 update to the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings.* This decision is considered final.

XI. Final List of Drugs Proposed for Placement on the NIOSH List of Hazardous Drugs

After consideration of all public comments received in the docket for this action, NIOSH will develop a final list of drugs to be placed on the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2018.* The 2018 Update will be published on the NIOSH website and announced in a **Federal Register** notice.

Dated: February 8, 2018.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2018–02957 Filed 2–13–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Office of Refugee Resettlement Cash and Medical Assistance Program Quarterly Report on Expenditures and Obligations.

OMB No.: 0970–0407.

Description: The Office of Refugee Resettlement (ORR) reimburses, to the extent of available appropriations, certain non-federal costs for the provision of cash and medical assistance to refugees and other eligible persons, along with allowable expenses for the administration of the refugee resettlement program at the State level. States, Wilson/Fish projects (alternative projects for the administration of the refugee resettlement program), and State Replacement Designees currently submit the ORR–2 Financial Status Report in accordance with 45 CFR part 92 and 45 CFR part 74. This proposed data collection would collect financial status data (*i.e.,* amounts of expenditures and obligations) broken down by the four program components: Refugee cash assistance, refugee medical assistance, health screening, and services for unaccompanied refugee minors as well as by program administration. This breakdown of financial status data on expenditures and obligations allows ORR to track program expenditures in greater detail to anticipate any funding issues and to meet the requirements of ORR regulations at 45 CFR 400.211 to collect these data for use in estimating annual costs of the refugee resettlement program. ORR must implement the methodology at 45 CFR 400.211 each year after receipt of its annual appropriation to ensure that the appropriated funds will be adequate for assistance to entering refugees. The estimating methodology prescribed in the ORR regulations requires the use of actual past costs by program component. In the event that the methodology indicates that appropriated funds are inadequate, ORR must take steps to reduce federal expenses, such as by limiting the number of months of eligibility for Refugee Cash Assistance and Refugee Medical Assistance. This proposed single-page report on expenditures and obligations will allow ORR to collect the necessary data to ensure that funds are adequate for the projected need and thereby meet the requirements of both the Refugee Act and ORR regulations.

Respondents: State Agencies, the District of Columbia, Replacement Designees under 45 CFR 400.301(c), and Wilson-Fish Grantees (State 2 Agencies) administering or supervising the administration of programs under Title IV of the Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR Financial Status Report Cash and Medical Assistance Program, Quarterly Report on Expenditures and Obligations	57	4	1.50	342

Estimated Total Annual Burden Hours: 342.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn:

[22] Harstad EB and Coleman R. Petition of Theravance Biopharma US, Inc. to Remove Telavancin from the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. February 28, 2017.

[23] NIOSH letter to Eric Harstad and Rebecca Coleman. April 12, 2017.