Specific questions of interest to the AHRQ include, but are not limited to, the following:

1. What clinical algorithms are used in clinical practice, hospitals, health systems, payment systems, or other instances? What is the estimated impact of these algorithms in size and characteristics of population affected, quality of care, clinical outcomes, quality of life and health disparities?
2. Do the algorithms in question 1 include race/ethnicity as a variable and, if so, how was race and ethnicity defined (including from whose perspective and whether there is a designation for mixed race or multiracial individuals)?
3. Do the algorithms in question 1 include measures of social determinants of health (SDOH) and, if so, how were these defined? Are these independently or collectively examined for their potential contribution to healthcare disparities and biases in care?
4. For the algorithms in question 1, what evidence, data quality and types (such as claims/utilization data, clinical data, social determinants of health), and data sources were used in their development and validation? What is the sample size of the datasets used for development and validation? What is the representation of Black, Indigenous, and People of Color (BIPOC) and what is the power to detect between-group differences? What methods were used to validate the algorithms and measure health outcomes associated with the use of the algorithms?
5. For the algorithms in question 1, what approaches are used in updating these algorithms?
6. Which clinical algorithms have evidence that they contribute to healthcare disparities, including decreasing access to care, quality of care or worsening health outcomes for BIPOC? What are the priority populations or conditions for assessing whether algorithms increase racial/ethnic disparities? What are the mechanisms by which use of algorithms contribute to poor care for BIPOC?
7. To what extent are users of algorithms including clinicians, health systems, and health plans aware of the inclusion of race/ethnicity or other variables that could introduce bias in these algorithms and the implications for clinical decision making? What evidence is available about the degree to which the use of clinical algorithms contributes to bias in care delivery and resulting disparities in health outcomes? To what extent are patients aware of the inclusion of race/ethnicity or other variables that can result in bias in algorithms that influence their care? Do providers or health systems communicate this information with patients in ways that can be understood?
8. What are approaches to identifying sources of bias and/or correcting or developing new algorithms that may be free of bias? What evidence, data quality and types (such as claims/utilization data, clinical data, information on social determinants of health), and data sources and sample size are used in their development and validation? What is the impact of these new approaches and algorithms on outcomes?
9. What challenges have arisen or can arise by designing algorithms developed using traditional biomedical or physiologic factors (such as blood glucose) yet include race/ethnicity as a proxy for other factors such as specific biomarkers, genetic information, etc.? What strategies can be used to address these challenges?
10. What are existing and developing standards (national and international) about how clinical algorithms should be developed, validated, and updated in a way to avoid bias? Are you aware of guidance on the inclusion or race/ethnicity, related variables such as SDOH, prior utilization, or other variables to minimize the risk of bias?
11. To what extent are users of clinical algorithms educated about how algorithms are developed or may influence their decision-making? What educational curricula and training is available for clinicians that addresses bias in clinical algorithms?

AHRQ is interested in all of the questions listed above, but respondents are welcome to address as many or as few as they choose and to address additional areas of interest not listed.

This RFI is for planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the Government to provide support for any ideas identified in response to it. AHRQ will use the information submitted in response to this RFI at its discretion and will not provide comments to any responder's submission. However, responses to the RFI may be reflected in future solicitation(s) or policies. The information provided will be analyzed and may appear in reports. Respondents will not be identified in any published reports. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. No proprietary, classified, confidential, or sensitive information should be included in your response. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public.

Dated: March 1, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–04509 Filed 3–4–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2020–0011]

Draft Infection Control in Healthcare Personnel: Epidemiology and Control of Selected Infections Transmitted Among Healthcare Personnel and Patients: Diphtheria, Group A Streptococcus, Meningococcal Disease, and Pertussis Sections; Re-Opening of Comment Period

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice with comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC), in the Department of Health and Human Services (DHHS), announces the re-opening of a docket to obtain a public comment on the *DRAFT Infection Control in Healthcare Personnel: Epidemiology and Control of Selected Infections Transmitted Among Healthcare Personnel and Patients: Diphtheria, Group A* Streptococcus, *Meningococcal Disease, and Pertussis Sections* (''*Draft Guideline*'').

DATES: Written comments must be received on or before May 4, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0011, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Attn: Docket No. CDC–2020–0011, Infection Prevention and Control Guidelines, 1600 Clifton Rd. NE, Mailstop H16–2, Atlanta, Georgia, 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For

access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Erin Stone, M.A., Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H16–2, Atlanta, Georgia, 30329; Email: *IPCGuidelines@cdc.gov;* Telephone: (404) 639–4000.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data related to the *Draft Guideline.*

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted in preparation of the final *Infection Control in Healthcare Personnel: Epidemiology and Control of Selected Infections Transmitted Among Healthcare Personnel and Patients* and may revise the *Draft Guideline* as appropriate.

Background

On February 26, 2020, CDC published a notice in the **Federal Register** requesting public comment on the 'Draft Infection Control in Healthcare Personnel: Epidemiology and Control of Selected Infections Transmitted Among Healthcare Personnel and Patients: Diphtheria, Group A *Streptococcus,* Meningococcal Disease, and Pertussis Sections' (85 FR 11084). Because the original notice was published in the early days of the COVID–19 pandemic, interested persons may not have had the opportunity to provide comment. For this reason, CDC has decided to re-open the comment period to provide the public with additional time to review the draft document and provide comment.

The *Draft Guideline* updates four sections of the *Guideline for Infection Control in Health Care Personnel, 1998* (''1998 Guideline''), *Part E: Epidemiology and Control of Selected Infections Transmitted Among Health Care Personnel and Patients,* and their corresponding recommendations in Part II of the *1998 Guideline:* ''4. Diphtheria;'' ''9. Meningococcal Disease;'' ''12. Pertussis;'' and ''18. *Streptococcus,* group A infection.'' The updated recommendations in the *Draft Guideline* are intended for use by the leaders and staff of Occupational Health Services (OHS) to facilitate providing occupational infection prevention and control (IPC) services to healthcare personnel (HCP) for the management of exposed or infected HCP who may be contagious to others in the workplace.

Since 2015, the Healthcare Infection Control Practices Advisory Committee (HICPAC) has worked with national partners, academicians, public health professionals, healthcare providers, and other partners to develop this *Draft Guideline* as a recommendation for CDC to update sections of the *1998 Guideline.* HICPAC includes representatives from public health, infectious diseases, regulatory and other federal agencies, professional societies, and other stakeholders.

The updated draft recommendations in this *Draft Guideline* are informed by reviews of the *1998 Guideline;* current CDC resources, guidance, and guidelines; and new resources and evidence, when available. This *Draft Guideline* and the updated final Guideline will not be a federal rule or regulation.

Dated: March 1, 2021.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2021–04515 Filed 3–4–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0033]

Morton Grove Pharmaceuticals Inc. et al.; Withdrawal of Approval of Seven Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of seven abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 5, 2021.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 065428	Cefprozil Tablets, 250 milligrams (mg) and 500 mg	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC., 6451 Main St., Morton Grove, IL 60053.
ANDA 077699	Mefloquine Hydrochloride (HCl) Tablets, 250 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 078383	Pioglitazone HCl Tablets, Equivalent to (EQ) 15 mg base; EQ 30 mg base; EQ 45 mg base.	Neopharma Inc., 211 College Road East, Suite 101, Princeton, NJ 08540.
ANDA 078953	Irinotecan HCl Injection, 40 mg/2 milliliters (mL) (20 mg/mL) and 100 mg/5 mL (20 mg/mL).	Do.
ANDA 079049	Alendronate Sodium Tablets, EQ 5 mg base; EQ 10 mg base; EQ 35 mg base; EQ 70 mg base.	Do.