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? 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]

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.
access to the docket to read background
documents or comments received, go to

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
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.

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.

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