The Focal Point: Advocacy & Legislative Update
October 2, 2018

FDA Updates 2018 Guidance Agenda

The Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) recently updated its 2018 Guidance Agenda. The agency is expected to issue an additional five guidances in the Blood and Blood Component category and three guidances in the Tissues and Advanced Therapies category in 2018.

FDA also renamed the proposed guidance on autologous serum eye drops, removing the words "and Biologics License Application" from the title of a proposed draft guidance. The current title is "Enforcement Policy Regarding Investigational New Drug Application Requirements for the Use of Autologous Serum Eye Drops for Lubrication for the Treatment of Dry Eye."

Two of the new draft guidances for blood establishments were also released:

- Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Draft Guidance for Industry (PDF - 97KB)

- Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV-I/II); Draft Guidance for Industry (PDF - 434KB)

CBER Secure Email Policy Took Effect October 1, 2018

CBER is increasing the use of secure email for regulatory communications to protect proprietary and company confidential information. Therefore, CBER's outgoing email communications that contain regulatory information will occur only with recipients who have a secure email account with FDA. Communication that is not regulatory in nature, such as logistics on how to get to the White Oak Campus, or general information that does not relate to regulatory information may be sent by unsecure email.

Additional resources to help you to easily set up secure email are available. If you do not already have secure email or have any related questions, please contact SecureEmail@fda.hhs.gov for further information. Please allow time, approximately a week, to establish an account. CBER will continue to communicate by hard copy letters sent through the U.S. Postal Service with those who do not have a secure email account.

On September 26, 2018, CBER hosted a webinar to discuss and answer questions about how to set up FDA secure email. This presentation will be available shortly.

FDA Issues New Draft Guidance on Insanitary Conditions at Compounding Facilities

FDA issued a revised draft guidance, "Insanitary Conditions at Compounding Facilities," intended to help compounding facilities identify and remediate insanitary conditions. This

guidance is also intended to help state regulatory agencies understand what the FDA considers to be unsanitary conditions that could cause a drug to become contaminated.

This guidance removes the provision that would have considered physicians who mix, compound, or repackage drugs in their offices as compounding pharmacies. FDA now states that it does not intend to take action against a physician who is compounding or repackaging a drug product, provided that such activities occur in the physician's office where the products are administered or dispensed to his or her own patients.

FDA Drafts Guidance on Monetary Penalties for Failing to Report Trials

Failing to report trial data to ClinicalTrials.gov may start to cost drug and device makers, according to a draft guidance entitled ''Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Draft Guidance for FDA Staff, Responsible Parties, and Submitters of Certain Applications and Submissions to FDA.''

The draft guidance is intended to address four issues:

1. How FDA's centers identify whether responsible parties have failed to submit required clinical trial registration and/or results information to ClinicalTrials.gov or submitted false or misleading information to the data bank, and whether submitters have failed to submit the certification required by the *Public Health Service Act* (PHS Act) to FDA or knowingly submitted a false certification to FDA.

2. Under what circumstances an FDA center may decide to seek civil monetary penalties against a responsible party or submitter.

3. The procedures that apply when an FDA center seeks civil monetary penalties.

4. What civil money penalty amounts may be assessed?

Submit either electronic or written comments on the draft guidance by November 20, 2018.

FDA Releases Draft Guidance on Adaptive Designs for Clinical Trials

FDA released a draft guidance for industry entitled ''Adaptive Designs for Clinical Trials of Drugs and Biologics.'' This document provides guidance to sponsors and applicants submitting investigational new drug applications (INDs), new drug applications (NDAs), biologics license applications (BLAs), or supplemental applications on the appropriate use of adaptive designs for clinical trials to provide evidence of the effectiveness and safety of a drug or biologic.

The guidance describes the basic principles for designing, conducting, and reporting the results from an adaptive clinical trial. The concepts discussed are also useful for early phase or exploratory clinical trials as well as trials conducted to satisfy postmarketing commitments or requirements. The draft guidance will replace the 2010 draft guidance for industry entitled ''Adaptive Design Clinical Trials for Drugs and Biologics.

FDA Issues Guidance on Evaluating the Benefit-Risk Profile of Medical Devices

FDA released a final guidance entitled "Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics."

This guidance document describes factors FDA considers when evaluating the benefit-risk profile of a device in comparison to a predicate device in a 510(k) when the device has the same intended use as the predicate device, and different technological characteristics that do not raise different questions of safety and effectiveness. This guidance can be helpful in situations when there is an increase in risk and increase or equivalent benefit, or a decrease in benefit and a decrease or equivalent risk when comparing a new device to a predicate device.

The 25-page guidance finalizes a draft version from 2014 and includes a flow chart and table meant to help determine when a benefit-risk assessment is recommended. The guidance is meant to be read in conjunction with FDA's 2014 510(k) program guidance, which details the agency's approach to evaluating substantial equivalence.

FDA Seeks Input to Expand Eligibility for Special 510(k)s

FDA released the draft guidance entitled "The Special 510(k) Program." FDA established the Special 510(k) Program to facilitate the submission, review, and clearance of changes to a manufacturer's own legally marketed predicate device. This draft is intended to update the policies set forth when the program was launched in 1998. At the time, modifications to the intended use of a device or any labeling changes were deemed inappropriate for special 510(k) submissions.

This draft guidance, when finalized, will provide the framework that FDA will use when considering whether a premarket notification (510(k)) is appropriate for review as a Special 510(k). This draft guidance is not final nor is it in effect at this time.

Submit comments by November 27, 2018, to ensure that FDA considers your comment before it begins work on the final version of this guidance.

President Signs FY2019 Funding Bill

On September 28, the President signed the Fiscal Year (FY) 2019 spending package minibus H.R. 6157 that includes the Labor, Health and Human Services, and Education (LHHS) and Defense spending bills, as well as a Continuing Resolution (CR) that funds the government through December 7 for any agencies for which FY2019 appropriations have not been finalized.

The spending bill increases the NIH's budget by $2 billion or 5.4 percent over its fiscal 2018 funding level to $39.08 billion and gives a $24.2 million (3.1 percent) National Eye Institute (NEI) increase to a funding level of $796.5 M.

The bill passed the House by a vote of 361 to 61 and passed the Senate in a 93-to-7 vote. It specifically includes an additional $425 million for Alzheimer's disease research for a total of $2.34 billion; a total of $429.4 million for the BRAIN initiative, a $29 million increase; and $376 million for the All of Us precision medicine study, $86 million more than in FY 2018.

CDC Message Regarding Ebola Outbreak in DRC

Due to the current Ebola outbreak in eastern Democratic Republic of Congo (DRC) and this year's earlier outbreak in western DRC, the CDC is reminding healthcare facilities to remain aware of the possibility of imported cases of viral hemorrhagic fevers or other infections in returning travelers.

For more information or resources regarding Ebola from the CDC, please click this link.

First Report on Detection of Dengue Virus in the Donor Cornea

A case report by Janani et al published ahead-of-print in *Cornea*, is the first report demonstrating the presence of infectious dengue virus (DENV) in a donor corneoscleral specimen from a cadaver with a history of viral hemorrhagic fever.