The Focal Point: Advocacy & Legislative Update
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CBER Publishes an Updated 2019 Guidance Agenda

FDA's Center for Biologics Evaluation and Research (CBER) updated the list of guidance they plan to release in 2019. The list includes eight guidance documents related to blood products and components, including a second draft guidance that will focus on revised preventive measures to reduce the possible risk of transmission of Creutzfeldt-Jakob Disease (CJD) and variant Creutzfeldt-Jakob Disease (vCJD) by blood and blood products. They have revised the title of the final guidance they plan to release on the use of serologic tests for HTLV I/II, incorporating recommendations for requalification of donors. They have already released the final guidance with recommendations for reducing the risk of transfusion-transmitted Babesiosis.

CBER expects to finalize the six gene therapy guidance documents which were published in July, including Human Gene Therapy for Retinal Disorders. Guidance on expedited programs for regenerative medicine therapies, evaluation of devices used with regenerative medicine advanced therapies, and standards development have already been released.

Other draft guidance are expected to deal with Interacting with the FDA on Complex and Innovative Clinical Trial Designs for Drugs and Biological Products.

Trump Issues Executive Order Limiting Federal Advisory Committees

President Trump issued an executive order mandating that all federal agencies evaluate the need for each of their advisory committees and eliminate at least one-third of current committees by Sept. 30. Additionally, the order limits the total number of advisory committees to 350. By Aug. 1, the secretary of each agency is required to submit a recommendation to the director of the Office of Management and Budget regarding whether each current advisory committee should continue.

Federal agencies should consider eliminating committees that have accomplished their stated objectives, those in which the subject matter or work of the committee has become obsolete, those whose primary functions have been assumed by another entity or those whose "cost of operation is excessive in relation to the benefits to the federal government." The executive order provides an exemption for advisory committees whose primary purpose is to provide scientific expertise to support agencies making decisions related to the safety or efficacy of products to be marketed to American consumers.

By Aug. 1, the secretary of each agency is required to submit a recommendation to the director of the Office of Management and Budget regarding whether each current advisory committee should continue. The executive order has the potential to affect advisory committees that are important to the eye banking community, such as the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), which advises the secretary of the Department of Health and Human Services (HHS) on issues related to the safety of blood, blood products, organs and tissues and CBER's Cellular, Tissue, and Gene Therapies Advisory Committee.

CBER Advanced Technologies Program

CBER has established the CBER Advanced Technologies Team (CATT) to promote dialogue, education, and input among CBER staff and between CBER and prospective innovators/developers

of advanced manufacturing technologies that are intended to be implemented in CBER-regulated products. As part of these efforts, the CATT will facilitate responses to inquiries or meeting requests from developers of these innovative technologies.

Details on this program and instructions for submitting inquiries can be found here.

FDA Finalizes Guidance on Advertising and Promotional Material Submissions

The FDA finalized guidance on the requirements and recommendations for submissions of promotional materials for prescription drugs and biological products, including the specific formats needed for use in the electronic common technical document (eCTD) as well as non-eCTD and non-electronic formats. This guidance finalizes the draft guidance issued in April 2015.

This guidance describes various types of regulatory submissions of promotional materials that firms submit to CDER and the Advertising and Promotional Labeling Branch in the Center for Biologics Evaluation and Research (CBER). References to ‘‘drugs’’ in this guidance also include human biological products that fall within the definition of ‘‘drug’’ under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(g).

Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs

Biologics License Applications and Master Files

FDA proposes to amend its regulations concerning the use of master files for biological products. The proposed rule would allow certain biological products, originally approved in a new drug application (NDA), to continue relying on a drug master file for information even after the NDA is deemed to be a license for a biological product on March 23, 2020.

The proposed rule also would codify FDA’s existing practice that information from a master file, including drug substance, drug substance intermediate or drug product information, may be relied on at the investigational phase of development for a biologic product subject to licensure under the PHS Act. It also codifies FDA’s existing practice that a biologic in a BLA may rely on a master file, except for information regarding a drug substance, drug substance intermediate or drug product.

FDA Releases 20 Years of Data on Medical Device Adverse Event Reports

The FDA recently ended its Alternative Summary Reporting (ASR) program for medical devices, revoked the related exemptions and released on its website all adverse event reports received under ASR exemptions from 1999 to 2019.

The ASR program was intended to be for “specific well-known and well-characterized events associated with specific devices,” and that exempted submissions excluded events where the device may have caused or contributed to a patient death. Instead device manufacturers quietly sent 5.7 million reports of injuries or malfunctions to the little-known database, instead of submitting them individually to its public database. A Kaiser Health News investigation revealed there were 176 deaths reported through the alternative summary reporting system.

To replace the ASR program, the FDA has launched the Voluntary Summary Reporting Program and plans to make its Manufacturer and User Device Experience (MAUDE) database – where all adverse events are stored – easier to use.

FDA Releases Draft ICH Safety Data, Bioanalytical Method Validation Guidelines

The FDA issued two draft International Council for Harmonisation (ICH) guidelines covering safety data collection and bioanalytical method validation for public consultation.

The guidelines which correspond to ICH's *E19 Optimisation of Safety Data Collection* and *M10 Bioanalytical Method Validation*, will be open for comment for 90 days. While both guidances are presented in ICH's original format for the consultation, FDA says the final versions will be reformatted to meet its good guidances practices and style requirements.

ICH E19
The ICH E19 guideline details a "selective approach" to gathering safety data in late-stage premarket and postmarket settings. The draft guidance is intended to advance important clinical research questions through the conduct of clinical investigations that collect relevant patient data, which will enable an adequate benefit-risk assessment of the drug for its intended use, while reducing the burden to patients from unnecessary tests that may yield limited additional information.

ICH M10
ICH's M10 guideline describes the method validation that is expected for bioanalytical assays that are submitted to support regulatory submissions. The guideline is applicable to the validation of bioanalytical methods used to measure concentrations of chemical and biological drug(s) and their metabolite(s) in biological samples (e.g., blood, plasma, serum, other body fluids or tissues) for nonclinical and clinical studies conducted to generate data to support regulatory submissions.

E19 Draft Guidance

M10 Draft Guidance

Charitable Giving Dropped After 2017 Tax Law

Donations to charities dropped by 1.7 percent last year after inflation, according to a report released this week by Giving USA. While corporate and foundation donations increased overall, giving by individuals dropped 3.4 percent last year. This is the first drop in charitable giving in the U.S. since the Great Recession, the report said.

Many charities warned that individual giving would decline as a result of the 2017 tax law that stopped millions of Americans from qualifying for the charitable tax deduction. The Tax Cuts and Jobs Act doubled the standard deduction to $24,000 for a couple, drastically reducing the number of households that itemized deductions. More than 45 million households itemized deductions on their tax returns in 2016, while that number is estimated to have dropped to approximately 16 to 20 million households in 2018.

RECALLS

Premier Pharmacy Labs Recalls All Unexpired Sterile Drug Product Lots

Premier Pharmacy Labs is voluntarily recalling all unexpired products, intended to be sterile, due to a lack of sterility assurance. The recall is in response to FDA concerns including insufficient environmental controls, potential cross contamination and lack of product specific process validations. The nationwide recall includes lots of sterile drug products to the consumer/user level and includes a number of ophthalmic drugs.

Premier Pharmacy Labs is notifying customers of the voluntary recall by certified letter. Customers who have any of the affected medications that are being recalled should immediately quarantine the product and discontinue use.

For more information on the specific lot numbers affected, please visit: https://premierpharmacylabs.com/urgent-product-recall/. Additionally, you may contact Premier Pharmacy Labs Monday through Friday, between 8:30 a.m. and 5:00 p.m. ET at 800-868-4978 or via e-mail at recalls@premierpharmacylabs.com to arrange return and credit.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online at: www.fda.gov/medwatch/report.htm

RXQ Compounding Recalls All Sterile Products within Expiry and Ceases Production

RXQ Compounding, LLC ("RXQ") is voluntarily recalling all sterile human and animal products within expiry to the user level due to lack of sterility process assurance associated with the production of the Company's sterile products. In addition, RXQ is voluntarily ceasing all sterile production at its current location in Athens, Ohio as RXQ transitions into the Company's new outsourcing facility.

Administration of a non-sterile product that is intended to be sterile by subcutaneous, intramuscular, intravenous or ocular routes of administration may result in serious injury or death. Report any adverse reactions experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program at: www.fda.gov/medwatch/report.htm

RXQ is notifying its customers by letter and is arranging for return of all recalled products. Hospitals and practitioners who have these products being recalled should stop using them immediately. For a full listing of the products being recalled, including lot numbers and expiration dates, please follow this link: https://rxqcompounding.com/Recall-List.pdf. Consumers with questions regarding this recall can contact RXQ between 9:00 a.m. and 5:00 p.m. ET at 740-331-4202 or via email at Brian.Post@RXQCompounding.com.