# The Focal Point: Advocacy & Legislative Update

**November 5, 2019**

## FDA Releases Guidance on Submitting Manufacturing Facility Information

The US Food and Drug Administration (FDA) finalized a guidance on the type of manufacturing facility information that should be included in applications submitted to the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.

FDA frequently receives questions regarding expectations for inclusion of manufacturing establishment information in applications and Form FDA 356h. Applications that contain extraneous information, misplaced or missing information could result in delays, Refusal to File or Refuse to Receive actions. This guidance offers detailed recommendations regarding the placement of facility information in both original and supplement applications.

Submission of Form FDA 356h serves as a summary of administrative information and should include complete information on the locations of all manufacturing, packaging, and control sites for both drug substance and drug product facilities associated with the application. This guidance addresses questions related to the inclusion and withdrawal of proposed commercial facilities and development facilities, the appropriate location within an application for facility information, and the type of facility information that should be included in applications.

Module 3 should contain all facilities listed on Form FDA 356h, as well as research and development manufacturing and testing sites that generated data in support of the application. This includes facilities that manufactured or tested any lots of the product.

This guidance applies to biologics license applications (BLA) products licensed under section 351 of the Public Health Service Act, including In-Vitro Diagnostics regulated as BLAs and drug products marketed (or to be marketed) under an NDA or an ANDA under the Federal Food Drug and Cosmetic Act. This guidance applies to all manufacturing locations, including facilities that perform functions under contract.

## FDA Modifies Listing of Recognized Consensus Standards

The FDA modified the listing of consensus standards developed by national and international organizations that the Agency is recognizing for use in premarket submissions and other requirements for devices.

This publication, entitled ‘‘Modifications to the List of Recognized Standards, Recognition List Number: 052’’ (Recognition List Number: 052), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency’s searchable database.

The publication contains two tables that include new entries to the list of recognized standards, and another list containing the withdrawal of standards and their replacement by others, if applicable, the correction of errors made by FDA in listing previously recognized standards and changes to the supplementary information.

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## FDA Revises Guidance on Postmarketing Studies and Clinical Trials

FDA revised its draft guidance on postmarketing studies and clinical trials for prescription drugs approved under Section 505(o)(3) of the *Federal Food, Drug, and Cosmetic Act* (FD&C Act) and biological products approved under section 351 of the Public Health Service Act (42 U.S.C. 262).

The guidance is being revised to detail how it determines if a postmarketing study or clinical trial will be required for a drug or biologic or whether postmarketing reports and the agency’s active postmarket risk identification and analysis (ARIA) system are sufficient to assess a product’s risks in the postmarket setting. The revision also reflects a SUPPORT Act provision that allows the agency to require postmarketing research to assess the possibility of reduction in a drug's efficacy.

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## FDA to Require Certain IND Safety Reports be Submitted to FAERS

FDA issued draft guidance requiring sponsors to submit investigational new drug (IND) safety reports for serious and unexpected suspected adverse events to the FDA Adverse Event Reporting System (FAERS) starting two years after the guidance is finalized. This safety information is expected to help the agency review and track potential safety signals during clinical trials, according to the FDA.

Currently, such reports are submitted to FDA in electronic common technical document (eCTD) format using PDF files, which FDA says are “inefficient and labor intensive” to review and track. For now, sponsors will be able to continue submitting such IND safety reports via eCTD, though sponsors may voluntarily submit the reports to FAERS before the requirement is in effect.

Once effective, the guidance will supersede FDA’s final guidance *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* for IND safety reports that fall within the scope of the new guidance.

## Trump Nominates Hahn to be FDA Commissioner

President Trump announced his intention to nominate radiation oncologist Stephen Hahn, MD, to lead the Food and Drug Administration.

Hahn, 59, is currently the chief medical officer at MD Anderson Cancer Center in Houston and specializes in lung cancer and sarcoma. He went to medical school at Temple University in Philadelphia, was a senior investigator at the National Cancer Institute (NCI) from 1989 to 1996 following his residency and served as Chair of the Department of Radiation Oncology at the University of Pennsylvania from 2005 to 2014.

Acting Commissioner Ned Sharpless will return to direct NCI, while Brett Giroir, assistant secretary for health at the US Department of Health and Human Services (HHS), will serve as acting FDA commissioner while Hahn's confirmation process occurs. If confirmed, Hahn would become the fourth agency leader in seven months.

## Hong Kong Proposes Regulatory Framework for ATPs

The government of Hong Kong recently introduced a bill to regulate medical products based on genes, cells and tissues, referred to as advanced therapy products (ATPs).

The bill specifies that ATPs should form a specific subset of pharmaceutical products under the Pharmacy and Poisons Ordinance and, as such, that regulatory requirements under that ordinance will apply to ATPs. Additionally, the bill stipulates that all facilities that manufacture ATPs must obtain a license in accordance with the ordinance. The bill also includes special labeling and record keeping requirements modeled after European Union laws to ensure product safety, quality and efficacy.

## NEI Grants Exclusive Patent License to CellRay

The National Eye Institute (NEI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to CellRay, LLC, (‘‘CellRay’’) located in New York, New York and its affiliates.

The prospective exclusive license territory may be limited to the United States for certain of the rights, or worldwide, and the field of use may be limited to the following:
“The development, production and commercialization of an autologous cell graft of manufactured Retinal Pigment Epithelium cell(s) on a biodegradable support scaffold transplanted sub-retinally for intra-ocular ophthalmic treatment of age-related macular degeneration in humans."

## KRS Global Biotechnology Recalls All Products

KRS Global Biotechnology, Inc. is voluntarily recalling all lots of unexpired human and animal drugs intended to be sterile to the consumer level. The products are being recalled due to lack of assurance of sterility. Read the FDA Alert for more information and the list of recalled products.

## FDA Comments on Potential Device Shortages with ETO Closures

Acting FDA Commissioner Ned Sharpless MD issued an Oct. 25 statement on potential medical device supply chain effects due to interruptions in ethylene oxide (ETO) sterilization services.

Concerns about ethylene oxide emissions have resulted in certain state actions against sterilization facilities that are currently impacting manufacturers' ability to use the ethylene oxide process to sterilize their medical devices. With the recent closure of a large ethylene oxide sterilization facility in Illinois (Sterigenics), the temporary closure of another large Sterigenics facility in Georgia, and with potential closure of a large Becton Dickinson sterilization facility in Georgia, the FDA is concerned about the future availability of medical devices and impending medical device shortages.

An FDA advisory meeting Nov. 6 and 7 will discuss use of ethylene oxide for device sterilization as industry stakeholders raise concerns about the consequences of a ban or significant restrictions.

## Allergan Recalls Xen45 Glaucoma Drainage Device

Allergan has voluntarily recalled all lots of XEN® Glaucoma Treatment System (XEN® 45 Gel Stent preloaded into a XEN® Injector). The company recommended surgeons postpone any upcoming surgeries using XEN and not implant any unused XEN devices currently in their practice/office/surgical suite/OR.

This recall is being conducted down to the Retail (Health Care Provider) Level. It is important to note that explanting implanted devices is not being recommended; this recall is a retrieval of un-implanted inventory.

During in-process inspection, 4 (four) units in an unreleased XEN® 45 lot were observed to have trace amounts of residual polishing compounds that are used in the needle sleeve manufacturing process. A review of the field safety reports has not detected any safety signals or adverse trends associated with the residual polishing compounds.

For any question regarding XEN or to report any adverse events, please contact Product Surveillance at 1-800-624-4261. Allergan anticipates resupply of XEN45® to the U.S. market in mid-December.

## CMS Releases Final Rule for ASC Payment

The Centers for Medicare & Medicaid Services (CMS) issued the Calendar Year (CY) 2020 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Policy Changes and Payment Rates final rule. CMS also released a fact sheet on this final rule.

The 2020 ASC Conversion Factor is $47.747 for ASCs meeting the quality reporting requirements.

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### Upcoming Events & Deadlines

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| November 6: | Webinar: Developing Ambassadors to Promote Your Mission |
| November 18: | 2020 Annual Meeting: Presentation Proposal Deadline |
| November 18: | Jachin Misko Memorial Scholarship Nomination Deadline |
| February 18: | 2020 Annual Meeting: Scientific Symposium Proposal Deadline |
| February 20-22: | Technician Education Seminar |
| March 6-7: | Eye Banker Leadership Program (Save the Date) |
| March 7-8: | Physician Leadership Program (San Antonio, TX) |
| June 17-20: | 2020 Annual Meeting (Dallas, TX) |