

North America Legal and Regulatory Affairs

Watchdog Update



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Health Canada

Datasource: <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radio-pharmaceuticals-genetic-therapies/what-new-biologics-radiopharmaceuticals-genetic-therapies-health-canada.html>

COVID-19

- [Australia, Canada, Singapore, Switzerland Consortium regulators pledge support to tackle COVID-19](#) [2020-05-05]
- [Engaging with international partners on COVID-19](#) [2020-04-30]
- [International Coalition of Medicines Regulatory Authorities \(ICMRA\) statement on COVID-19](#) [2020-04-29]
- [Management of clinical trials during the COVID-19 pandemic: Notice to clinical trial sponsors](#) [2020-04-22]
- [Health Product Advertising Incidents related to COVID-19](#) [2020-04-16]
- [Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19](#) [2020-04-05]
- [Exceptional importation and sale of drugs and biocides against COVID-19](#) [2020-04-05]

Review Decisions:

- [Summary Basis of Decision \(SBD\) for Galli Eo](#) [2020-04-20]
- [Summary Basis of Decision \(SBD\) for Netspot](#) [2020-04-20]
- [Summary Basis of Decision \(SBD\) for Trazimera](#) [2020-04-20]
- [Summary Basis of Decision \(SBD\) for Ultomiris](#) [2020-04-20]

- [Updated Notice: Regulatory Enrolment Process \(REP\) Non-Functional Pilot for Clinical Trials](#) [2020-04-22]
- [Weekly Drug NOC updates](#)
- [Association Meetings: Biologics and Genetic Therapies Directorate](#)
- Consult the [Drug and Health Product Register](#) regularly for [Regulatory Decision Summaries](#) for drugs.
- Consult the [Drug and Health Product Register](#) regularly for Post-Authorization Activity Tables, which are added to [Summary Basis of Decision documents](#) for drugs.
- [Updated List of Drugs for an Urgent Public Health Need](#) [2020-04-24]
- [Updated Register of Certificates of Supplementary Protection and Applications](#) [2020-05-12]

FDA

Datasource: <https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/whats-new-biologics>

COVID-19

- Updated Information for Blood Establishments Regarding the Novel Coronavirus (COVID-19) Outbreak
- Investigational COVID-19 Convalescent Plasma; Guidance for Industry (Updated: May 1, 2020)
- Recommendations for Investigational COVID-19 Convalescent Plasma
- Letter to CBER Sponsors, Applicants and Regulated Entities on COVID-19 (update)
- Coronavirus (COVID-19) | CBER-Regulated Biologics

Guidelines

Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components; Guidance for Industry

Upcoming Conferences/Transcripts from Past Conferences and/or Public Hearings

- Transcript for the Facilitating End-to-End Development of Individualized Therapeutics Public Workshop [Mar 3, 2020]

Updated Approvals

2020 Biological License Application Approvals

2020 Biological License Application Supplement Noteworthy Approvals

2020 Biological Device Application Approvals

Approval Letters:

- May 11, 2020 Approval Letter - Anti - M (Murine Monoclonal IgG) STN#125308-56
- May 7, 2020 Approval Letter - Blood Grouping Reagent Anti-e P3GD512 + MS16 + MS21 + MS63
- May 7, 2020 Approval Letter - Reagent Red Blood Cells A1 Cells / B Cells
- May 7, 2020 Approval Letter - Blood Grouping Regents Anti-A, Anti-B, Anti-A,B, Anti-D, Anti-D (PK 1), Anti-D (PK 2), Anti-E, Anti-e, Anti-C, Anti-c, and Anti-K
- May 6, 2020 Approval Letter - HEPLISAV-B
- May 5, 2020 Approval Letter - VAXELIS
- May 1, 2020 Approval Order - INTERCEPT Blood System for Plasma
- April 23, 2020 Approval Letter - MenQuadfi
- April 23, 2020 Approval Letter - Anti-D (RH1) IgM/IgG
- April 21, 2020 Approval Letter - AFSTYLA
- April 14, 2020 Approval Letter - FluMist

Current Submissions and Applications

- Complete List of Licensed Products and Establishments
- Complete List of Substantially Equivalent 510(k) Device Applications
- Complete List of Currently Approved Premarket Approvals (PMAs)
- Complete List of Currently Approved NDA and ANDA Application Submissions

Current Letters:

- May 11, 2020 Untitled Letter - Sparrow Health & Performance, LLC
- April 28, 2020 Untitled Letter - BrioMD
- April 27, 2020 Untitled Letter - Henry N. Small, MD, PA
- April 27, 2020 Untitled Letter - Infuze MD
- April 10, 2020 Untitled Letter - Kimera Labs, Inc.

Job Vacancy:

CBER Vacancy: Staff Fellow/Visiting Associate: Viral Vaccines