Compliance Program Guidance Manual

Chapter 45. Biological Drug Products

Inspection of Biological Drug Products (CBER)

7345.848

시행 일자(Implementation Date): 2010년 10월 1일

종료 일자(Completion Date): 계속(Ongoing)

제품 코드(Product Codes):		프로그램/업무 코드 (Programs/Assignment Codes):
57A	Antitoxins (e.g., Botulism Antitoxin)/ Antivenins (e.g., snake, spider)	45848A Pre-License Inspection - Allergenics
57B	Immunization Toxoids (e.g., Diphtheria Toxoid, Tetanus Toxoid)	45848F Level 1 CGMP Inspection - Allergenics
57C	Viral Vaccines (e.g., Rabies, Yellow Fever, Small Pox, Influenza Vaccines)	45848G Level 2 CGMP Inspection - Allergenics
57E	In-Vivo Diagnostic Products (e.g., Tuberculin PPD (skin test))	45848B Pre-License Inspection - Vaccines
57G	Allergenic Products (e.g., Allergenic Extracts, animal allergens, venoms)	45848C Level 1 CGMP Inspection - Vaccines
57H	Bacterial Vaccines/Antigens (e.g., Pneumococcal Vaccine, Meningococcal Polysaccharide Vaccine)	45848D Level 2 CGMP Inspection – Vaccines
57I	Multiple Vaccine/Multiple Antigen Preparations (e.g., Measles, Mumps, Rubella Vaccine; Diphtheria, Tetanus, and Pertussis Vaccine)	45848H Off Year Flu PAC
57M	Human Hematopoietic Cells (e.g., Umbilical Cord Blood Stem Cells)	42848A Pre-License Inspection - Plasma Derivatives
57N	Human Cell and Gene Therapies (e.g., Cell Therapies, Vectors, Genetically Modified Cells)	42848F Level 1 CGMP Inspection - Plasma Derivatives
57U	Blood Derivatives (e.g., Albumin, Immune	42848G Level 2 CGMP

Globulin	Inspection - Plasma Derivatives
57Y Biological In-Vivo and In-Vitro Diagnostic Products Not Elsewhere Classified (N.E.C.)	42848B Pre-License Inspection – Recombinant Analogues
	42848C Level 1 CGMP Inspection – Recombinant Analogues
	42848D Level 2 CGMP Inspection – Recombinant Analogues
	41848A Pre-License Inspection - Somatic Cell and Gene Therapy
	41848F Level 1 CGMP Inspection - Somatic Cell and Gene Therapy
	41848G Level 2 CGMP Inspection - Somatic Cell and Gene Therapy
	41848B Pre-License Inspection – Licensed Hematopoetic Progenitor Cell
	41848C Level 1 CGMP Inspection - Licensed Hematopoetic Progenitor Cell
	41848D Level 2 CGMP Inspection - Licensed Hematopoetic Progenitor Cell

현장 보고 기준(FIELD REPORTING REQUIREMENTS)

Send Establishment Inspection Reports (EIRs) that contain issues requiring policy development or clarification to the Center for Biologics Evaluation and Research (CBER) for review. Send the EIR and relevant exhibits (electronically, if possible), to CBERInspections@fda.hhs.gov, or by mail to:
정책 개발이나 명확화가 필요한 이슈가 있는 EIR을 CBER에 보내 CBER의 검토를 받는다. EIR과 관련 근거 문서를 가능하면 CBERInspections@fda.hhs.gov로 전자적으로 발송하거나 다음 주소를 수취인으로 하여 우편으로 발송한다.

Division of Inspections & Surveillance, HFM-650
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448

국내 시판후 실사(Domestic Post-Market Inspections):

Inspections classified NAI and VAI: Notify CBER, Office of Compliance and Biologics Quality (OCBQ), Division of Inspections and Surveillance (DIS) HFM-650 at CBERInspections@fda.hhs.gov when EIRs are available in Turbo EIR. Do not submit exhibits unless specifically requested.
NAI 및 VAI로 분류되는 실사: 터보 EIR에서 EIR이 제공되는 경우, CBER, OCBQ, DIS HFM-650(CBERInspections@fda.hhs.gov)에 통보한다. 별도로 요청하지 않으면, 근거 문서를 제출하지 않는다.

Inspections classified OAI: Send a complete copy of the EIR, including exhibits, and the FACTS coversheet with endorsement and classification to OCBQ/DIS/HFM-650.
OAI로 분류되는 실사: 근거 문서를 포함해 EIR 전체 사본과 배서 및 분류 내용이 포함된 FACTS 커버시트를 OCBQ/DIS/HFM-650으로 발송한다.

Regardless of classification, send the complete original report, with exhibits, to the home district.
분류 유형과 상관 없이, 전체 원본 보고서를 근거 문서와 함께 HD(home district)로

발송한다.

해외 시판후 실사(Foreign Post-Market Inspections):

CBER acts as the “home district” for foreign inspections of CBER-regulated products. Send the complete original EIR, with exhibits, to OCBQ/DIS/HFM-650, regardless of recommended classification.
CBER 규제 대상 제품의 해외 실사에 대해서는 CBER이 "HD(home district)" 역할을 한다. 권고 분류 유형과 상관 없이, 전체 원본 EIR를 근거 문서와 함께 OCBQ/DIS/HFM-650로 발송한다.

허가/승인전 실사(Pre-license and Pre-approval Inspections)

CBER acts as the "home district" for all pre-license and pre-approval inspections of CBER-regulated products, whether foreign or domestic. Send a copy of the signed original EIR and Form FDA 483 to OCBQ/DIS/HFM-650 and include the complete original EIR, with exhibits, in the license application file documents as per current CBER standard operating procedures.
국내 실사나 해외 실사와 상관 없이, CBER 규제 대상 제품의 모든 허가/승인전 실사에 대하여 CBER이 "HD" 역할을 한다. 서명을 한 원본 EIR과 FDA 483 문서 사본을 OCBQ/DIS/HFM-650으로 발송하고, 근거 문서를 포함해 원본 EIR 전체를 CBER SOP에 따라 라이선스 신청 파일 문서에 포함시킨다.

실사 보고 - EIR 배서 섹션(Inspection Reporting – Endorsement Section of EIR)

The FACTS endorsement (Inspection Summary field) shall include the inspection level and the systems inspected for a level II inspection in addition to the information specified in the Investigations Operations Manual (IOM).
FACTS 배서 부분(실사 요약 항목)에 IOM에 규정된 정보 이외에도, 실사 레벨과 레벨 II 실사인 경우에 실사 대상 시스템을 기술한다.