

미국 화장품 및 OTC Drug 인허가 대행기관 목록 안내

2020.3.18.

- 미국으로의 화장품 및 OTC Drug 수출이 점차 증가함에 따라 우리 협회에서는 미국 인허가 대행기관에 대한 많은 문의를 받고 있습니다.
 - ※ 자외선차단제, 비듬 샴푸, 여드름 제품, 제한제, Astringent 효과가 있는 Skin Protectant(Salicylic acid가 들어간 제품)는 미국에서는 OTC Drug로 분류됨
- 이에 우리 협회에서는 회원사에게 편의를 제공하여 드리는 차원에서 미국 인허가 대행기관을 안내하여 드리게 되었습니다.
- 아래의 대행기관은 우리 협회가 공식적으로 인정 혹은 추천하는 기관은 아니므로, 각 회원사에서는 이를 참고자료로만 활용하여 주시기 바랍니다.
- 본 안내를 통하여 우리 협회에서 얻게 되는 경제적인 이익은 일절 없으며, 대행기관과의 실제 업무 진행 시 발생하는 그 어떤 문제에 대하여 우리 협회에서는 민·형사상의 책임을 지지 않음을 알려드립니다.
- 대행사에 대한 상세 정보는 붙임1을 참고하시어 대행기관측으로 직접 문의하여 주시기 바랍니다.

미국 화장품 및 OTC Drug 인허가 대행기관
dicentra
EAS Consulting Group, LLC
EcoMundo
FDA Atty
FDAImports.com, LLC
ICRS (International Cosmetics & Regulatory Specialists, LLC)
MTOM Global
TSG Consulting (Technology Sciences Group, Inc.)

※ 회사명 알파벳 순 정렬

[붙임1]

회사명	dicentra
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1

소개

회사명 (NAME)	dicentra		대 표 자 (PRESIDENT)	Alicja Wojewnik
창립일 (FOUNDATION DATE)	2012		웹사이트 (WEBSITE)	www.dicentra.com
총 사원수 (NUMBER OF EMPLOYEE)	25		화장품 관련 실무인원수 (NUMBER OF EMPLOYEES FOR COSMETICS)	25
소재지 (LOCATION)	주 소 (ADDRESS)	7 St. Thomas St. Unit 603, Toronto, Ontario, M5S2B7, Canada		
	전화번호 (PHONE)	416-361-3400	이메일 (E-MAIL)	info@dicentra.com
회사 소개 및 특징 (COMPANY INTRODUCTION)	<p>dicentra is a contract research organization and professional consulting firm that specializes in addressing all matters related to safety, quality and compliance for all product categories in the life sciences and food industries.</p> <p>We evaluate, implement, and provide all the necessary support for your products and operations, allowing you to gain market access while building confidence in your brand. We achieve this through our four business divisions:</p> <ul style="list-style-type: none"> • Life Sciences Consulting • Food Safety & Quality Consulting • Global Certifications • Clinical Trials <p>Since our inception in 2002, we have completed over 18,000 projects and serviced over 1200 companies internationally. Our clients look to us to help protect their bottom line while integrating our team as a part of theirs. This is a result of the continuous efforts we make to provide the highest level of client care.</p>			

The regulations governing cosmetics contain potential pitfalls, particularly in the areas of proper classification and appropriate claims. dicentra's experience, together with our ongoing relationships with cosmetic trade associations and government agencies, keeps us ahead of the curve with respect to cosmetic regulatory affairs.

Cosmetic Services for the United States

Whether the cosmetic is manufactured in the U.S. or imported from abroad the product must be in compliance with the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and the Fair Packaging and Labeling Act (FP&L Act). Our services include:

- Product Classification
- FDA Cosmetic Product Ingredient Statements (CPIS) Form 2512 Filing
- Advising on product claims, ingredient listings and warning declarations
- Reviewing scientific studies, data and information to substantiate product claims and establish ingredient safety
- Advising on compliant labeling and advertising strategies
- Providing guidance on compliance issues relating to cGMPs
- Assistance in registering products in the Voluntary Cosmetic Registration Program

Cosmetic Services for Canada

- Confirmation that product is a cosmetic
- Advising on product claims, ingredient listings and warning declarations
- Reviewing scientific studies, data and information to substantiate product claims and establish ingredient safety
- Advising on compliant labeling and advertising strategies
- Providing guidance on compliance issues relating to GMPs
- Cosmetic Notification Form preparation and submissions
- Compliant and accurate French translation for labels

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사업 범위

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
Regulatory consulting firm specializing in Health Canada and FDA regulations	dicentra provides regulatory consulting compliance services with respect to Health Canada and FDA regulations in every health product category (including cosmetics and OTC drugs).

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담당자

부서명 (DEPARTMENT)	Life Sciences	성명 (NAME)	Karol Wojewnik
직함 (POSITION)	Vice President	전화 (PHONE)	416-361-3400 x 229
팩스 (FAX)	416-361-3304	이메일 (E-MAIL)	karol@dicentra.com
구사 가능 언어 (COMMUNICATION LANGUAGE)	English		

회사명

EAS Consulting Group, LLC

1

소개

회사명 (NAME)	EAS Consulting Group, LLC		대표자 (PRESIDENT)	Dean Cirotta
창립일 (FOUNDATION DATE)	October, 2006		웹사이트 (WEBSITE)	www.easconsultinggroup.com
총 사원수 (NUMBER OF EMPLOYEE)	10 Staff 150 Independent Consultants		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	<Cosmetic Independent Consultants> 4 Cosmetic Label Experts 2 Ingredient and Testing Experts <OTC Independent Consultants> 8 General Regulatory, ingredients and labeling Experts 20 cGMP (audits/Mock-FDA Inspections) 2 Importation Compliance 8 Laboratory and Quality Control
소재지 (LOCATION)	주소 (ADDRES S)	1700 Diagonal Road, Suite 750, Alexandria, VA 22314		
	전화번호 (PHONE)	+1- 571 -447-5505	이메일 (E-MAIL)	dcirotta@easconsultinggroup.com
회사 소개 및 특징 (COMPANY INTRODUCTION)	EAS Consulting Group, LLC is a leading provider of regulatory services to the pharmaceutical, medical device, food, dietary supplement, tobacco and cosmetic industries. Originally founded in 1960, the firm has more than 50 years of experience assisting clients in developing regulatory strategies, implementing quality assurance programs, filing regulatory submissions and ensuring compliance with FDA regulations. Employing a unique team of former Food and Drug Administration (FDA) officials and industry experts, EAS offers unparalleled expertise with many consultants having more than 30 years of FDA experience.			

In November 2019, EAS joined the Certified Family of Companies, expanding capabilities for both companies in laboratory testing and comprehensive consulting services for FDA regulated industries.

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사업 범위

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
US Food and Drug(FDA) Regulatory Consulting	Provider of regulatory services to industries regulation by FDA: cosmetic, pharmaceutical, medical device, food, dietary supplement, and tobacco industries.
Laboratory Testing	EAS Consulting Group's parent company, Certified Laboratories, performs testing for microbiological contamination in cosmetics

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담당자

부서명 (DEPARTMENT)	Labeling and Cosmetic Consulting Services	성명 (NAME)	Cathryn W Sacra
직함 (POSITION)	Director, Labeling and Cosmetic Services	전화 (PHONE)	+1 571-447-5505
팩스 (FAX)		이메일 (E-MAIL)	csacra@easconsultinggroup.com
구사 가능 언어 (COMMUNICATION LANGUAGE)	English		

회사명

Ecomundo

1

소개

회사명 (NAME)	에코문도(EcoMundo)		대표자 (PRESIDENT)	Pierre Garçon
창립일 (FOUNDATION DATE)	회사창립일: 2007.09.26 해외화장품인증 업무개시일: 2013		웹사이트 (WEBSITE)	http://www.ecomundo.eu
총 사원수 (NUMBER OF EMPLOYEE)	70명	화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	15명	
소재지 (LOCATION)	주소 (ADDRESS)	북미지사: 4284 Rue de la Roche, Montréal, QC H2J 3H9, Canada 서울지사: 서울특별시 중구 삼일대로 343 대신파이낸스센터		
	전화번호 (PHONE)	서울지사: 010 3093 6246	이메일 (E-MAIL)	korea@ecomundo.eu
회사 소개 및 특징 (COMPANY INTRODUCTION)	<p>에코문도는 미국, 캐나다 그리고 유럽 등 세계 코스메틱 시장 진출을 준비하는 국내 기업을 위한 Total Solution을 제공합니다.</p> <p>에코문도는 40여명이 넘는 인하우스 전문가를 통해 미국 OTC/VCRP 등록, 캐나다 CNF 등록, 유럽 CPNP등록, 화학물질의 REACH 등록, 위험물질 관리 및 등록 서비스를 제공하고 있습니다.</p> <p>특히 저희 에코문도는 에코문도 자체 개발 프로그램인 COSMETIC-FACTORY를 통해 글로벌 코스메틱 그룹 및 국내외 중소기업체에 정확하고 투명한 등록 서비스를 제공하고 있습니다.</p>			

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사업 범위

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
<ul style="list-style-type: none"> • 캐나다/미국/유럽 /브라질 화장품 규정에 따른 제품 등록 • MSDS/CLP 준수 (향수, 디퓨저 등) • SVHC/BIOCIDES 관리 • REACH 등록 	<p>에코문도는 10년 이상 등록 경험을 쌓아온 Regulatory Compliance Consultant 전문 기업으로 미국 및 캐나다로의 제품 시판을 위한 자료 취합부터 등록까지 정확하고 체계적인 시스템을 이용한 통합 서비스를 제공합니다.</p> <p>미국 수출을 위한 VCRP와 OTC 제품등록, 그리고 캐나다 수출을 위한 Cosmetic Compliance (CNF) 등록을 제품 Formula 및 라벨 검토 과정을 통해 도와드리고 있습니다.</p> <p>북미 현지의 노하우를 축적한 북미지사와 한국의 프로젝트 매니저가 등록 전과정을 도와드리고 있습니다.</p> <p>한국의 프로젝트 매니저는 현지와의 시차, 언어, 문화차이로 인한 어려움을 해소해 드리며, 한국 고객에게 맞는 맞춤형 서비스를 제공합니다. 한국 고객의 입장에서 생각하고, 한국 현지 커뮤니케이션으로 궁금한 점을 즉각적으로 해결해드립니다.</p>

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담당자

부서명 (DEPARTMENT)	한국지사	성명 (NAME)	신선미
직함 (POSITION)	한국지사 대표	전화 (PHONE)	010 3093 6246
팩스 (FAX)		이메일 (E-MAIL)	sshin@ecomundo.eu
구사 가능 언어 (COMMUNICATION LANGUAGE)	영어(English) / 프랑스어(French) / 한국어(Korean)		

회사명

FDA Atty

1

소개

회사명 (NAME)	CIHCC, LLC d/b/a FDA Atty		대표자 (PRESIDENT)	Marc C. Sanchez, Esq.
창립일 (FOUNDATION DATE)	October 2010		웹사이트 (WEBSITE)	www.fdaatty.com
총 직원수 (NUMBER OF EMPLOYEE)	3		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	3
소재지 (LOCATION)	주소 (ADDRESS)	1717 Pennsylvania Ave., Suite 1025 Washington, D.C. 20006 U.S.A.		
	전화번호 (PHONE)	+1-202-765-4491	이메일 (E-MAIL)	msanchez@fdaatty.com
회사 소개 및 특징 (COMPANY INTRODUCTION)	<p>A leading regulatory law firm advising both foreign and domestic healthcare, cosmetic, and food companies with primary expertise involving the United States Food and Drug Administration and secondary experience with the USDA.</p> <p>The regulatory acumen extends over a broad range of issues involving drugs, biologics, devices, dietary supplements, medical foods, and a variety of enforcement actions</p>			

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사업 범위

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
FDA Regulatory Law Firm	Specializing and exclusively working in FDA regulatory matters. Expert knowledge in all FDA subjects including cosmetics, OTC drugs, registration (VCRP and CDER Direct), ingredient classification, labeling compliance, and import holds (Notices of Action, Form 766, Import Alerts, etc.) among other topics.

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담당자

부서명 (DEPARTMENT)	Regulatory Counsel	성명 (NAME)	Marc C. Sanchez, Esq.
직함 (POSITION)	President	전화 (PHONE)	202-765-4491
팩스 (FAX)		이메일 (E-MAIL)	msanchez@fdaatty.com
구사 가능 언어 (COMMUNICATION LANGUAGE)	English		

회사명**FDImports.com, LLC****1****소개**

회사명 (NAME)	FDImports.com		대 표 자 (PRESIDENT)	Benjamin L. England
창립일 (FOUNDATION DATE)	February 29, 2008		웹사이트 (WEBSITE)	Fdimports.com
총 사원수 (NUMBER OF EMPLOYEE)	30		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	10
소재지 (LOCATION)	주 소 (ADDRESS)	810 Landmark Drive, Suite 126, Glen Burnie, Maryland, USA 21061		
	전화번호 (PHONE)	+1-410-220-2800	이메일 (E-MAIL)	contact@fdimports.com
회사 소개 및 특징 (COMPANY INTRODUCTION)	<p>FDImports's regulatory specialists and affiliated attorneys (with the law firm Benjamin L. England & Associates) represent proven consulting and legal experience, integrated into a single source for solving the problems involved in bringing products to the highly-regulated United States market.</p> <p>Our team has over 100 years of direct FDA experience, helping manufacturers, distributors, importers and exporters of cosmetics, dietary supplements, drugs, and other regulated goods.</p> <p>Our services include responding to FDA Warning Letters, Import Alerts, Detentions, and Refusals. We provide facility registration, US Agent and US permit services. We counsel companies on GMP compliance, marketing claims and product labels.</p>			

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사업 범위

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
Cosmetics imports to the USA	FDA regulations apply different marketing requirements to cosmetics than to drugs. FDA regulates some products as drugs even though the product manufacturers or importers initially thought the products could be marketed as cosmetics. This often happens because the products contain active drug ingredients or labeling or marketing claims on the cosmetic labeling or in the product's Internet advertising or promotional materials that are drug claims. Our firm helps companies comply with US regulations for cosmetic imports.
OTC and other drug and homeopathic imports to the USA	There are many FDA requirements that apply to drugs that do not apply to foods, dietary supplements or cosmetics. However, the degree of FDA regulation depends upon the class of drug. Our regulatory consultants help foreign drug companies comply with US regulations for over-the-counter, prescription, APIs, and homeopathic drugs.

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담당자

부서명 (DEPARTMENT)	Client Services Team	성명 (NAME)	
직함 (POSITION)		전화 (PHONE)	+1-410-220-2800
팩스 (FAX)		이메일 (E-MAIL)	contact@fdainports.com
구사 가능 언어 (COMMUNICATION LANGUAGE)	English		

회사명

ICRS (International Cosmetics & Regulatory Specialists, LLC)

1

소개

회사명 (NAME)	ICRS (International Cosmetics & Regulatory Specialists, LLC)		대표자 (PRESIDENT)	Janet Winter Blaschke
창립일 (FOUNDATION DATE)	1997		웹사이트 (WEBSITE)	www.intlcosmetics.com
총 인원수 (NUMBER OF EMPLOYEE)	6		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	6
소재지 (LOCATION)	주소 (ADDRESS)	947 Manhattan Beach Blvd., Manhattan Beach, CA 90266, USA		
	전화번호 (PHONE)	+1-310-545-3223	이메일 (E-MAIL)	info@intlcosmetics.com
회사 소개 및 특징 (COMPANY INTRODUCTION)	<p>Delivering regulatory solutions to brand owners all over the world since 1997. We specialize in USA FDA compliance for cosmetics of all categories, and OTC drugs. We provide FDA registrations, Drug Facts labeling, GMP compliance, and cosmetic labeling requirements. Located in California, we deliver solutions to even the most challenging state-specific regulations. Often not recognized, local regulations can be just as important as FDA's. Chemists & experts on staff can help you avoid enforcement on complex issues such as Proposition 65 and Volatile Organic Compounds (VOCs).</p>			

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사업 범위

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
USA OTC Drug product compliance	FDA registrations, GMP compliance, OTC Drug requirements-labeling, claims, ingredient requirements
USA Cosmetic requirements	Product registrations at State and Federal levels, Product labeling requirements, California compliance: VOCs, Proposition 65, Safe Cosmetics Act, claims and ingredient acceptability.

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담당자

부서명 (DEPARTMENT)	Regulatory	성명 (NAME)	Georgia Boehm
직함 (POSITION)	VP Regulatory Affairs	전화 (PHONE)	+1-310-545-3223
팩스 (FAX)		이메일 (E-MAIL)	info@intlcosmetics.com
구사 가능 언어 (COMMUNICATION LANGUAGE)	English, Spanish, French		

회사명**MTOM GLOBAL INC.****1****소개**

회사명 (NAME)	국문: (주) 엠톰 글로벌 영문: MTOM GLOBAL INC	대 표 자 (PRESIDENT)	존 권 (John Kwon)
창립일 (FOUNDATION DATE)	May 2017	웹사이트 (WEBSITE)	www.mtomglobal.com
총 사원수 (NUMBER OF EMPLOYEE)	15	화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	5
소재지 (LOCATION)	주 소 (ADDRESS)	580 Sylvan Avenue, Englewood Cliffs, NJ 07632, U.S.A.	
	전화번호 (PHONE)	+1-347-927-6262	이메일 (E-MAIL) john@mtomglobal.com
회사 소개 및 특징 (COMPANY INTRODUCTION)	We are a total solution provider of import & export services, distribution, sales & marketing, product development, contract manufacturing, industry certifications, and U.S. FDA, USDA, CBP regulatory consulting for health/beauty/wellness global brands from various countries like Korea, Japan, Italy, and Canada.		

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사업 범위

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
Distribution & Marketing	We represent and market global brands from Korea, Japan, Italy and Canada to mass market through various distribution channels both on and offline.
Regulatory & Consulting	We provide Federal and State level (U.S. FDA, USDA, CBP, California State) regulatory compliance services and consulting for both domestic and international clients.

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담당자

부서명 (DEPARTMENT)	FDA Consulting	성명 (NAME)	John Kwon
직함 (POSITION)	Executive Director	전화 (PHONE)	+1-347-927-6262
팩스 (FAX)	+1-800-774-8218	이메일 (E-MAIL)	john@mtomglobal.com
구사 가능 언어 (COMMUNICATION LANGUAGE)	Korean, English		

회사명

TSG Consulting
(Technology Sciences Group, Inc.)

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소개

회사명 (NAME)	TSG Consulting		대표자 (PRESIDENT)	Ryan Gaunt Erin Tesch, Managing Director
창립일 (FOUNDATION DATE)	1992		웹사이트 (WEBSITE)	https://www.tsgconsulting.com
총 사원수 (NUMBER OF EMPLOYEE)	35 (North America) 60+ (Global)		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	20
소재지 (LOCATION)	주소 (ADDRESS)	1150 18th Street NW, Suite1000, Washington, DC 20036, USA		
	전화번호 (PHONE)	202-828-8990	이메일 (E-MAIL)	info@tsgconsulting.com
회사 소개 및 특징 (COMPANY INTRODUCTION)	<p>Technology Sciences Group (TSG) is a global consulting firm operating for 27 years providing state, federal, and international expertise on a wide range of scientific and regulatory issues primarily to the regulated chemicals market.</p> <p>With experts in regulatory affairs, chemistry, toxicology, biology, microbiology, ecotoxicology, environmental fate, efficacy, residue and metabolism, and risk assessment, TSG provides services in support of the registration, compliance, and defense of a broad range of product categories and markets including cosmetics, over-the-counter drugs, chemical, consumer, industrial, agricultural, food and beverage, and medical device.</p> <p>At our core, we specialize in providing the regulatory and scientific support necessary to market such products at the state, federal, and international level.</p>			

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사업 범위

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
Cosmetic (USA)	<p>Cosmetic products and ingredients in the U.S. are regulated under the Federal Food, Drug and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). The Food and Drug Administration (FDA) holds cosmetic companies responsible for ensuring that their products are safe and properly labeled and are not misbranded as drug products. In addition to FDA, cosmetics and personal care products are subject to state regulations.</p> <p>Services Include:</p>

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담당자

부서명 (DEPARTMENT)	Business Development	성명 (NAME)	Dave Rottjakob
직함 (POSITION)	VP, Business Development	전화 (PHONE)	202-828-8990
팩스 (FAX)		이메일 (E-MAIL)	info@tsgconsulting.com
구사 가능 언어 (COMMUNICATION LANGUAGE)	English		