미국 화장품(MoCRA) 및 OTC Drug 인허가 대행기관 목록 안내

2024.01.02.

- 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 기관 은 아니므로, 각 회원사에서는 이를 참고자료로만 활용하여 주시기 바랍니다.
- 본 안내를 통하여 우리 협회에서 얻게 되는 경제적인 이익은 일절 없으며, 대행기관과의 실제 업무 진행 시 발생되는 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
Registrar Corp.
TSG Consulting (Technology Sciences Group, Inc.)

※ 회사명 알파벳 순 정렬

dicentra

1 회사 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	주소 7 St. Thomas St. Unit (ADDRESS) M5S2B7, Canada		t 603, Toronto, (Ontario,
(LOCATION)	전화번호 (PHONE)	416-361-3400	이메일 (E-MAIL)	info@dicentra.com
	dicentra is a contract research organization and professional consulting			

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.

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:

회사 소개 및 특징

(COMPANY INTRODUCTION)

- Life Sciences Consulting
- Food Safety & Quality Consulting
- Global Certifications
- Clinical Trials

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.

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 Unites 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

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).

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		

EAS Consulting Group, LLC

회사명 (NAME)	EAS Consulting Group, LLC		대 표 자 (PRESIDENT)	Dean Cirotta
창립일 (FOUNDATION DATE)	October, 2006		웹사이트 (WEBSITE)	www.easconsultinggroup.co
총 사원수 (NUMBER OF EMPLOYEE)	10 Staff 150 Independent Consultants		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	<pre><cosmetic consultants="" independent=""> 4 Cosmetic Label Experts 2 Ingredient and Testing Experts <otc consultants="" independent=""> 8 General Regulatory, ingredients and labeling Experts 20 cGMP (audits/Mock-FDA Inspections) 2 Importation Compliance 8 Laboratory and Quality Control</otc></cosmetic></pre>
소재지	주 소 (ADDRES S)	1700 Diagonal Roa	ad, Suite 750, Al	exandria, VA 22314
(LOCATION)	전화번호 (PHONE)	+1- 571 -447-5505	이메일 (E-MAIL)	dcirotta@easconsultingroup.
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.

2 주요 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

부서명	Labeling and Cosmetic	성명	Cathryn W Sacra
(DEPARTMENT)	Consulting Services	(NAME)	Cathlyn W Sacia
직함	Director, Labeling and	전화	11 571 447 5505
(POSITION)	Cosmetic Services	(PHONE)	+1 571-447-5505
팩스		이메일	csacra@easconsultinggro
(FAX)		(E-MAIL)	up.com
구사			
가능 언어	Faciliah		
(COMMUNICATION	English		
LANGUAGE)			

Ecomundo

회사명 (NAME)	에코문도(EcoMundo)		대 표 자 (PRESIDENT)	Michel Hemberg
창립일 (FOUNDATION DATE)	회사창립일: 2007.09.26 해외화장품인증 업무개시일: 2013		웹사이트 (WEBSITE)	https://blog.naver.com/ ecomundoseoul
총 사원수 (NUMBER OF EMPLOYEE)	200명		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	30명
소재지 (LOCATION)	주 소 (ADDRESS) 전화번호 (PHONE)	Canada 서울지사: 서울특별시	de la Roche,	,
회사 소개 및 특징 (COMPANY INTRODUCTION)	는 국내 기업 에코문도는 록, 캐나다 관리 및 등록 특히 저희 이를 통해 글로	성을 위한 Total Solution 40여명이 넘는 인하우 CNF 등록, 유럽 CPNI 록 서비스를 제공하고 있	n을 제공합니다. 스 전문가를 통해 P등록, 화학물질의 났습니다. 나체 개발 프로그램	스메틱 시장 진출을 준비하 미국 화장품 및 OTC 등 리 REACH 등록, 위험물질 범인 COSMETIC-FACTORY I에 정확하고 투명한 등록

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)		
	에코문도는 10년 이상 등록 경험을 쌓아온 Regulatory Compliance		
• 캐나다/미국/유	Consultant 전문 기업으로 미국 및 캐나다로의 제품 시판을 위한 자료		
럽/브라질 화장품	취합부터 등록까지 정확하고 체계적인 시스템을 이용한 통합 서비스		
규정에 따른 제품	를 제공합니다.		
등록			
	미국 수출을 위한 화장품 및 OTC 제품등록, 그리고 캐나다 수출을 위		
• MSDS/CLP 준수	한 Cosmetic Compliance (CNF) 등록을 제품 Formula 및 라벨 검토 과		
(향수, 디퓨저 등)	정을 통해 도와드리고 있습니다.		
•	북미 현지의 노하우를 축적한 북미지사와 한국의 프로젝트 매니저가 등		
SVHC/BIOCIDES 관리	록 전과정을 도와드리고 있습니다.		
• REACH 등록	한국의 프로젝트 매니저는 현지와의 시차, 언어, 문화차이로 인한 어려		
	움을 해소해 드리며, 한국 고객에게 맞는 맞춤형 서비스를 제공합니다.		
	한국 고객의 입장에서 생각하고, 한국 현지 커뮤니케이션으로 궁금한		
	점을 즉각적으로 해결해드립니다.		

부서명 (DEPARTMENT)	한국지사	성명 (NAME)	박지민
직함 (POSITION)	세일즈 매니저	전화 (PHONE)	010 9922 6246
팩스 (FAX)	N/A	이메일 (E-MAIL)	jpark@ecomundo.eu
구사 가능 언어 (COMMUNICATION LANGUAGE)	영어(Engl	lish) / 한국어(k	Korean)

FDA Atty

회사명 (NAME)	CIHCC, LLC	C d/b/a FDA Atty	대 표 자 (PRESIDENT)	Marc C. Sanchez, Esq.
창립일 (FOUNDATION DATE)	October 2010		웹사이트 (WEBSITE)	www.fdaatty.com
총 사원수 (NUMBER OF EMPLOYEE)	3		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	3
소재지	주소 1717 Pennsylvania Ave., Suite 1025 Washington, D.C. 2000(ADDRESS) U.S.A.			Washington, D.C. 20006
(LOCATION)	전화번호 (PHONE)	+1-202-765-4491	이메일 (E-MAIL)	msanchez@fdaatty.com
회사 소개 및 특징 (COMPANY INTRODUCTION)	domestic primary ex Administra The regulations	tion and secondar atory acumen exte	netic, and fo the United Sta y experience v ands over a ba , devices, o	ood companies with ates Food and Drug with the USDA. road range of issues dietary supplements,

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, ingredient classification, labeling compliance, and import holds (Notices of Action, Form 766, Import Alerts, etc.) among other topics.

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		

FDAImports.com, LLC

회사명 (NAME)	FDAImports.	com	대 표 자 (PRESIDENT)	Benjamin L. England
창립일 (FOUNDATION DATE)	February 29, 2008		웹사이트 (WEBSITE)	Fdaimports.com
총 사원수 (NUMBER OF EMPLOYEE)	30		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	10
소재지	주 소 (ADDRESS)	주소 810 Landmark Drive, Suite 126, Glen Burnie, Maryland, USA		
(LOCATION)	전화번호 (PHONE)	+1-410-220-2800	이메일 (E-MAIL)	contact@fdaimports.co
회사 소개 및 특징 (COMPANY INTRODUCTION)	FDAImports'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. 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. 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.			

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.

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

ICRS (International Cosmetics & Regulatory Specialists, LLC)

회사명 (NAME)	ICRS (International Cosmetics & Regulatory Specialists, LLC)		대 표 자 (PRESIDENT)	Janet Winter Blaschke
창립일 (FOUNDATION DATE)	1997		웹사이트 (WEBSITE)	www.intlcosmetics.co m
총 사원수 (NUMBER OF EMPLOYEE)	6		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	6
소재지	주 소 (ADDRESS)	947 Manhattan Beach USA	Blvd., Manhatta	n Beach, CA 90266,
(LOCATION)	전화번호 (PHONE)	+1-310-545-3223	이메일 (E-MAIL)	info@intlcosmetics.co m
회사 소개 및 특징 (COMPANY INTRODUCTION)	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).			

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.

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		

MTOM GLOBAL INC.

회사명 (NAME)		국문: (주) 엠톰 글로벌 영문: MTOM GLOBAL INC		좐 권 (John Kwon)
창립일 (FOUNDATION DATE)	May 2017		웹사이트 (WEBSITE)	www.fdara.com
총 사원수 (NUMBER OF EMPLOYEE)	15		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	7
	주 소 (ADDRESS)	NEVADA OFFICE: 1016	99 Riverview Dr. 7512 USA	
소재지 (LOCATION)	전화번호 (PHONE)	NEW YORK OFFICE Tel +1-347-927-6262 NEVADA OFFICE Tel +1-725-222-6787 (CAMPUS)	이메일 (E-MAIL)	john@mtomglobal.com info@fdara.com
회사 소개 및 특징 (COMPANY INTRODUCTION)	We provide regulatory guidance and compliance services to domestic and international companies. We work closely with the U.S. Food and Drug Administration (FDA) and other government agencies — EPA, USDA, CBP, etc. Food, Drugs, OTCs, Medical Devices, Cosmetics, Dietary Supplements, Tobacco Products, Radiation—Emitting Products, Pesticides, Chemicals, etc. We are also a total solution provider for your import & export trade, customs clearance, inspection, distribution, sales & marketing, product development, private labeling, industry/government certifications, detention services.			

- ▶ 미 FDA 인증-허가 전문 컨설팅 및 대행 서비스 제공
- ▶ 식품, 화장품, 의약품, 의료기기 등 해외 규격 인증-허가 서비스 제공
- ▶ 수출, 수입통관, 거부/억류 대응, 검수, 유통, 물류 서비스 제공

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
Distribution & Marketing	We represent major global (North/South America, Asia, Europe) brands to mass market through various distribution channels both online and offline.
Regulatory & Consulting	We provide Federal and State levels (U.S. FDA, EPA, USDA, CBP, etc.) regulatory guidance and compliance services to domestic and international clients.

부서명 (DEPARTMENT)		성명 (NAME)	John Kwon
직함 (POSITION)	Director of Regulatory Affairs & Compliance	전화 (PHONE)	+1-347-927-6262
팩스 (FAX)	+1-888-380-8918	이메일 (E-MAIL)	john@mtomglobal.com
구사 가능 언어 (COMMUNICATION LANGUAGE)	Korean, English		

Registrar Corp (주)레지스트라

회사명 (NAME)	Registrar ((주)레지스	•	대 표 자 (PRESIDENT)	David Lennarz 데이비드 레너즈
창립일 (FOUNDATION DATE)	2003		웹사이트 (WEBSITE)	www.registrarcorp.com
총 사원수 (NUMBER OF EMPLOYEE)	320 team members worldwide 전세계 320여 명의 임직원		화장품 및 OTC Drug 관련 실무인원수 (NUMBER OF PRACTITIONERS FOR COSMETIC & OTC Drugs)	40여 명
	주 소 (ADDRESS)	144 Research Drive, H	ampton, Virginia,	USA
소재지 (LOCATION)	전화번호 (PHONE)	+1-757-876-0992	이메일 (E-MAIL)	dlennarz@registrarcor p.com info@registrarcorp.co m
회사 소개 및 특징 (COMPANY INTRODUCTION)	Registrar keeps consumers healthy and safe by helping food, cosmetic, medical device, and drug companies meet global compliance requirements. We do this by providing software solutions, regulatory expertise, and training that makes compliance quick and easy. 레지스트라는 식품, 화장품, 의료기기, 의약품 업체가 글로벌 준수 요건을 충족할 수 있도록 지원하여 소비자들의 건강과 안전을 지키고 있습니다. 레지스트라에서는 빠르고 쉬운 규제 준수를 실현하는 소프트웨어 솔루션, 규제 전문가, 트레이닝 프로그램을 제공하고 있습니다.			

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
Regulatory services, software, and training 규제 서비스, 소프트웨어, 교육	미국 FDA 규제 요건에 대하여 알아보고자 하는 한국의 현재 고 객사 및 잠재적인 고객사를 위하여 (주)레지스트라는 한국 지사 담당자를 두어 지원하고 있습니다.

부서명 (DEPARTMENT)	Sales, Marketing, Customer Support 영업, 마케팅, 고객지원	성명 (NAME)	Sunhee Yim 임선희
직함 (POSITION)	Regulatory Advisor 규제 자문	전화 (PHONE)	+82-10-6854-2019
팩스 (FAX)		이메일 (E-MAIL)	korea@registrarcorp.com
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TSG Consulting (Technology Sciences Group, Inc.)

회사명 (NAME)	TSG Consulting		대 표 자 (PRESIDENT)	Ryan Gaunt Erin Tesch, Managing Director
창립일 (FOUNDATION DATE)	1992		웹사이트 (WEBSITE)	https://www.tsgconsul ting.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	주소 1150 18th Street NW, Suite1000, (ADDRESS) Washington, DC 20036, USA			
(LOCATION)	전화번호 (PHONE)	+1-202-828-8990	이메일 (E-MAIL)	info@tsgconsulting.co
회사 소개 및 특징 (COMPANY INTRODUCTION)	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. 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			

사업 범위 (BUSINESS SCOPE)	업무 내용 (JOB DESCRIPTION)
Cosmetic (USA)	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.

부서명 (DEPARTMENT)	Business Development	성명 (NAME)	Dave Rottjakob
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구사 가능 언어 (COMMUNICATION LANGUAGE)	English		