Kyper & Associates, LLC

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Kyper & Associates, LLC is an association of independent consultants providing regulatory and technical services to the medical device industry. Most are former FDA Center for Devices and Radiological Health (CDRH) managers and scientific reviewers. Their extensive experience and expertise enable our clients to meet FDA regulatory requirements and market quality products in the most cost-effective and expedient manner possible. The firm's services include the interpretation, applicability and enforcement of FDA laws, regulations, guidances and policies; development of regulatory and testing strategies; preparation / critique of 510(k), IDE, and PMA submissions, reclassification petitions, required reports, responses to FDA deficiency and warning letters, and other submissions; development / assessment of labeling, advertisements, and other promotional materials and programs; preparation for and representation at FDA meetings; QSR//MDR compliance audits; due diligence investigations; litigation assistance; and expert testimony.

Charles H. Kyper, RAC, the firm's founder and principal consultant, started his 28-year FDA career in 1966 as a FDA field office investigator (drug specialist) and later served as a compliance officer in the then FDA Bureau of Drugs. In 1977 he initiated and directed the Industry Services Staff in the CDRH Office of Small Manufacturers Assistance. He had significant input into the development of regulations and programs implementing the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990. He was the Director of the Premarket Approval Staff (1981-1990) and Assistant Director for Reclassification and Compliance (1990-1994) in the CDRH Office of Device Evaluation (ODE). In the latter capacity he was the primary ODE resource for regulatory guidance and was the ODE liaison with the CDRH Office of Compliance for regulatory matters involving device marketing submissions, labeling, advertising and promotion. From 1985 to 1994 he was also the CDRH Coordinator for its device master file, color additive, environmental assessment, and patent term restoration programs. Mr. Kyper is a member of the Regulatory Affairs Professionals Society (RAPS). He is Regulatory Affairs Certified (RAC) by RAPS and served on the Board of Editors (1997-2001) of Regulatory Affairs Focus published monthly by RAPS. His publications include numerous feature articles in device trade journals, the FDA Premarket Approval Application (PMA) Manual, and FDA guidances on device labeling, device master files, and other device-related matters. He has delivered more than 100 presentations at conferences, workshops, and FDA advisory committee meetings on a wide range of device regulatory topics.

As a consultant he has extensive experience in providing expert reports, depositions and expert court testimony in numerous and varied litigation matters involving medical devices. He represents plaintiffs and defendants based upon the merits of the case.

Charles H. Kyper, RAC

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March, 1996 to Present — Kyper & Associates, L.L.C.

Founder and Principal Consultant of this medical device regulatory consulting firm. This association of independent consultants with extensive FDA or industry experience provides a comprehensive range of regulatory and technical services including: citation and interpretation of applicable FDA laws, regulations, guidances, and policies; compliance and testing strategies; preparation or review of device marketing submissions [510(k)/IDE/PMA/PDP], required reports, and responses to FDA correspondence; preparation for FDA and advisory panel meetings: due diligence investigations; QSR and MDR compliance audits; litigation assistance; and expert testimony. Member of the Regulatory Affairs Professionals Society (RAPS). I am Regulatory Affairs Certified (RAC) by RAPS and served from 1997 to 2001 on the Board of Editors of *Regulatory Affairs Focus*\ published monthly by RAPS.

August, 1994 March, 1996 — C.L. McIntosh & Associates, Inc.

Senior Regulatory Consultant for a medical device consulting fir located in Rockville, Maryland. Work experience included preparation or review of device marketing submissions, device labeling. MDR reports, and replies to FDA correspondence; development of regulatory and testing strategies; citation and interpretation of applicable FDA laws, regulations, guidances and policies; FDA meeting preparation; due diligence investigation; and GMP audits.

June, 1966 August, 1994 — Food and Drug Administration

FDA Center for Devices and Radiological Health (CDRH)

September, 1993 August, 1994 — Associate Director for Regulatory Affairs, Division of Small Manufacturers Assistance, Office of Health and Industry Programs

Senior advisor to the staff on device marketing-related FDA laws, regulations, guidances and policies. Responded to the most complex inquiries from industry, Congress, health care providers, and other FDA offices. Continued my involvement in developing plans and regulations implementing the device marketing-related provisions under the Safe Medical Devices Act of 1990 (SMDA). Drafted

guidances on device classification and reclassification and drafted a revised medical device kit policy. Nominated in 1990 by the CDRH Director for recognition as the FDA National Expert on Medical Device Regulation. Retired from FDA in August 1994.

July, 1990
September, 1993 — Assistant Director for Reclassification and Compliance
Office of Device Evaluation

Office of Device Evaluation (ODE) liaison with the Office of Compliance re enforcement activities involving device marketing, labeling, advertising and promotion. Primary resource for ODE and other FDA staff re. FDA device laws, regulations, policies and procedures. Coordinated review of device reclassification petitions. Developed CDRH implementation of SMDA provisions re classification reconsideration of preamendments and transitional class III devices. Coordinated drafting of rulemaking requiring PMA approval for high priority preamendments class III devices. Drafted proposed rule to clarify the PMA supplement requirements. ODE representative on regulation drafting task forces re restricted devices, temporary suspension of PMA approval, humanitarian use devices, and device advertising and promotion. Developed guidances on device labeling and preparation of PMA manufacturing information Critiqued the 1982 PMA approval for an injectable collagen product following the State of Texas ban of the product and Congressional staff criticism of the PMA review and approval. Excerpts from my in-depth review appeared in the national press. Prepared FDA's first order for the temporary suspension of the 1991 PMA approval for an ophthalmic surgical aid subsequently withdrawn by the manufacturer following an informal hearing.

March, 1981
July, 1990 — Director, Premarket Approval Staff, Office of Device Evaluation

Coordinated and oversaw the scientific, regulatory and administrative review of premarket approval applications (PMAs) and product development protocols (PDPs). Substantially contributed to the 1986 final order for the PMA procedural regulation and authored the Premarket Approval (PMA) Manual and the Device Master File guidance. Coordinator for CDRH device master file, color additive, environmental assessment and patent term restoration programs. Routinely made presentations at FDA and trade association sponsored conferences, seminars and workshops re. PMA procedures, device clinical study design, device labeling, and device master files.

August, 1977
March, 1981 — Chief, Industry Services Staff, Office of Small Manufacturers Assistance

Assisted in initiating this office as required under the Medical Device Amendments of 1976. Provided technical and other nonfinancial assistance to promote industry understanding of, and compliance with, this legislation and the implementing regulations and policies. Project Manager for industry conferences and workshops, guidances, and responses to industry inquiries. As the designated industry ombudsman, reviewed and commented on drafts of proposed and final regulations. Principal FDA speaker on a wide range of the legislative provisions at industry conferences and workshops.

Center for Drug Evaluation and Review

April, 1972
August, 1977

Chief, Inspection Review Staff, Division of Methadone Monitoring, Office of Compliance

Enforced regulation (modified IND/NDA) establishing limited distribution for the use of methadone in analgesia and drug abuse treatment. Presided at most informal hearings. FDA-designated expert for all four methadone-related injunctions. Processed regulatory actions involving the submission to FDA of fraudulent drug-related information or the misuse of any drug that presented a serious risk to public health.

February, 1977
June, 1977
(120-day detail)
for

Division of OTC Drug Evaluation

Reviewed industry submissions of safety and efficacy information

OTC drugs. Prepared and/or edited the OTC Panel reports and tentative final monographs for various OTC drug classes. Prepared the Panel report that led to the OTC use of hydrocortisone ointments.

August, 1976
October, 1976
(120-day detail)

Special Assistant to the Director, Bureau of Drugs

Coordinated and monitored the office's daily workflow. Briefed the Bureau Director regarding proposed policy statements. Commented on drafts of proposed and final regulations.

FDA District Offices

February, 1968
April, 1972

Investigator (Drug Specialist), Philadelphia and Baltimore District Offices

Conducted GMP inspections and other investigations of drug manufacturers and clinical investigators. Served as the Philadelphia District Office Recall and Emergency Coordinator for 6 months. Transferred

to the Baltimore District Office in September 1970. Coordinated all drug monitoring and surveillance programs in both district offices.

June, 1966 – February, 1968 — Investigator (Generalist), Baltimore District Office

Conducted inspections and investigations of a wide variety of FDA-regulated industries. Selected to transfer to the Philadelphia District Office to participate in its Intensified Drug Inspection Program.

EDUCATION

Formal

Loyola College (Baltimore, Maryland)
B.S. Biology, 1962
Freshman year at the University of Michigan (Ann Arbor, MI) and 20 credits of science from Johns Hopkins University (Baltimore, MD)

Graduate studies in the biomedical sciences at the University of Maryland School of Medicine (1962-1963) and the University of West Virginia School of Dentistry (1964-1966)

Technical

Dickerman-Gottlieb Food and Drug Law Course
Update Course: February, 1979 (40 hours)
Basic Course: March, 1975 (40 hours)

George Washington University (Washington, D.C.)
Biomedical Equipment in Health Care Facilities
March, 1979 (16 hours)

University of Tennessee School of Pharmacy (Memphis, TN)
Advance Course for Drug Inspectors: Parenterals
June-July, 1971 (80 hours)

University of Pittsburgh School of Pharmacy (Pittsburgh, PA)
Advance Course for Drug Inspectors: Pharmacology and Experimental Therapeutics; April, 1970 (120 hours)

University of Rhode Island School of Pharmacy (Kingston, RI)
Basic Course for Drug Inspectors; July-August, 1968 (160 hours)

Western Executive Seminar Center (Denver, CO)
Managerial Competencies for Executives; March 1990 (80 hours)

Significant In-House FDA Training:
Statistical Methodology in Clinical Trials; 1982 (12 hours)
Experimental Statistics for Biomedical Scientists; 1982 (32 hours)

AWARDS

1994 Special Recognition Award (Participation in Workshop on Acupuncture)
1993 Group Recognition Award [ODE 515(b) Task Force]
1993 Certificate of Recognition (Sustained Contributions in Implementing the Safe Medical Devices Act of 1990)
1989 Commissioner's Special Citation (Sustained Superior Performance and Resourcefulness)
1987 Commissioner's Special Citation (Exceptional Performance in Focusing On and Eliminating the Statutory Backlog in Premarket Approval Applications)

PUBLICATIONS

CDRH Premarket Approval Manual (1986)

Medical Device & Diagnostic Industry feature articles:
January 1982: The 510(k) Route to the Marketplace
July 1995: Preamendment Class III Devices: The FDA Strategy
July 1996: FDA's Resurrected Device Classification Program

Regulatory Affairs Professionals Society Regulatory Affairs Focus
February 1997: CDRH Policies on Use of Confidential Industry Information Need Tightening
July 1997: FDA Regulation of Tobacco Products: Its Possible Impact on Medical Device Use and Advertising
March 1998: Fiscal Year Comparisons of FDA Enforcement Actions
February 1999: General Provisions of FDAMA: A Status Report
February 2000: FDAMA Implementation: Medical Device Update
October 2000: Least Burdensome or Business as Usual?
December 2001: Medical Device Labeling and the Duty to Warn
January 2003: Medical Device Recalls and Market Withdrawals: Does Your Firm Know the Difference and Act Accordingly?

The Validation Consultant
June 1997: Device Labeling Preparation

Journal of cGMP Compliance
October 1997: Control of Investigational Devices