



FMDIC, INC.

CHARTER

HISTORICAL PERSPECTIVE:

The US Food and Drug Administration (FDA) Medical Device Industry Coalition was formed by officials from FDA Dallas District, Texas Department of Health and medical device industry association representatives. The Coalition was established to facilitate effective interaction between the medical device industry and FDA's district field office.

MISSION:

To facilitate the availability of safe and effective medical devices through enhanced communications and cooperation between the medical device industry, appropriate state agencies, and the FDA.

ORGANIZATIONAL PURPOSE:

- 1) To facilitate the availability of safe and effective medical devices through enhanced communications and cooperation between industry, appropriate state agencies, academics and the U.S. Food and Drug Administration; and
- 2) To develop and disseminate educational programs and information on issues important to the medical device industry; and,
- 3) To receive and administer funds for such purposes, all for the public welfare; and,
- 4) In general, to exercise any, all, and every power for which a non-profit corporation organized under the applicable provisions of the Texas Business Organization Code, all for social welfare of the general public, can be authorized to exercise, but only to the extent the exercise of such powers are in furtherance of exempt purposes.

ORGANIZATIONAL STRUCTURE:

The Coalition is an independent, non-profit organization composed of individuals from the medical device industry, state and federal government representatives and academic members. The names of medical device industry representatives, from within Dallas District, will be submitted to the Coalition by medical device associations for consideration. Nominees recommended for membership will be submitted on

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association letterhead to the Coalition co-chairs via the Coalition secretary. The Coalition will, subsequently, vote on submitted membership proposals.

Government representatives may include officials from state Departments of Health, representatives from the Dallas District Office (the medical device program manager, senior medical device investigators and district managers) and representatives from the Southwest Regional Office. The Coalition may also include academic members. There are no fees or membership dues collected from the members of the Coalition.

ELECTION OF OFFICERS:

The Coalition will elect two individuals from the current membership to serve as co-chairs for one, two-year term. Co-chairs may serve successive terms. One co-chair will be selected from medical device industry association or academic members and one co-chair will be selected from regulatory members.

MEETINGS:

The Coalition will formally meet quarterly at an agreed upon site. Designated members are expected to attend or to send an alternate in order to maintain active status.

ETHICS:

Individual members will refrain from performing any action, during a Coalition sponsored activity, from which they will derive private gain e.g. solicitation of services.

Version	Description of Change	Co-Chair	Co-Chair	Secretary
15 Mar 2013	New Document – FMDIC, INC.	<i>Jeff Manely</i>	<i>A. Salinas</i>	<i>C. [Signature]</i>