



Pico Pan de Azúcar en la Sierra Nevada del Cocuy, Colombia.

MINISTRY FOR HEALTH

**NATIONAL INSTITUTE FOR DRUG AND
FOOD SURVEILLANCE
COLOMBIA**

INVIMA



NOHRA LUCIA RODRIGUEZ M.

**HEAD OF THE MEDICAL DEVICES AND HEALTH
PRODUCTS COMPLIANCE UNIT**



SANITARY SURVEILLANCE FOR MEDICAL DEVICES

SINGAPORE, MAY 2002



INVIMA IS AN INSTITUTION:

- NATIONAL AND PUBLIC**
- SCIENTIFIC AND TECHNICAL**
- ENFORCEMENT CAPACITY**
- ADMINISTRATIVE INDEPENDANT**
- VINCULATED TO THE MINISTRY OF HEALTH**
- DULY ESTABLISHED BY THE LAW 100, 1993,**
- STARTED OPERATIONS FEBRUARY 1995.**



MISSION

- TO PROTECT THE INDIVIDUAL AND COLLECTIVE HEALTH OF COLOMBIAN COMMUNITY
- REPRESENTING THE POPULATION RIGHTS
- DEMANDING THAT THE HEALTH AND COMFORT DON'T BE THREATENED BY UNSAFE PRODUCTS

VISION

NATIONAL COVERAGE INSTITUTION

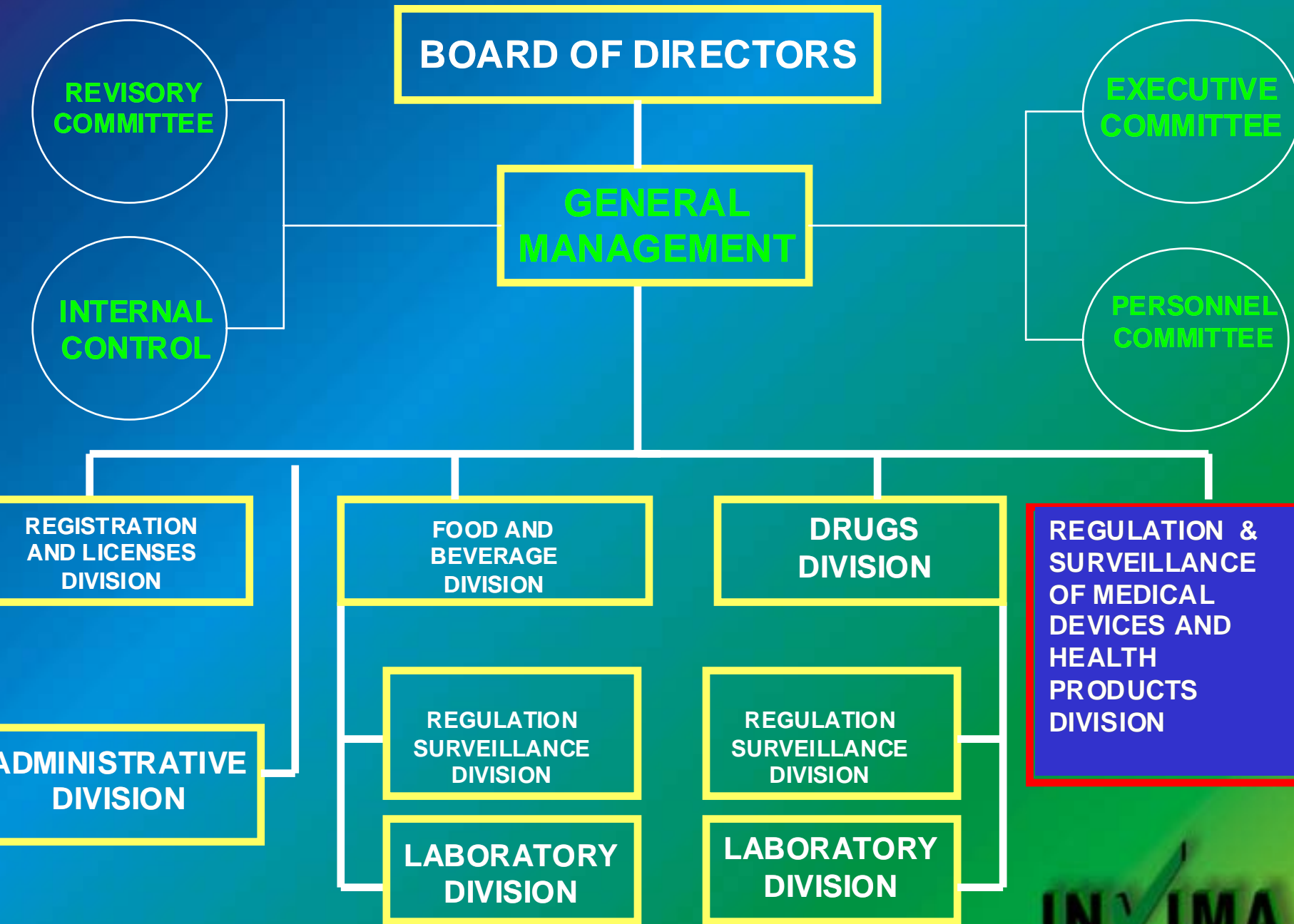
WEB IMPLEMENTED INFORMATION

IMMEDIATE AND EFFECTIVE ACTION

SCIENTIFIC BACKGROUND

FUNCTIONS

**IMPLEMENT THE MINISTRY OF HEALTH POLICY
DEVELOP, DISEMINATE AND UPDATE TECHNICAL
PROCEDURES AND INFORMATION
ISSUE AND APPROVE HEALTH LICENSE
CONDUCT THE SANITARY SURVEILLANCE PROGRAM
APPLY SANITARY SAFETY MEASURES
FUNCTION AS LABORATORY OF REFERENCE
TRAIN, UPDATE SURVEILLANCE STAFF
ADVISE LOCAL HEALTH AUTHORITES
SUPERVISE COMPLIANCE WITH SANITARY
SURVEILLANCE AND QUALITY CONTROL PROGRAMS**



SURVEILLANCE



REGISTRATION AND
LICENSES DIVISION

DEVICES DIVISION

HEALTH LICENSE

TO CONTROL MANUFACTURING,
IMPORTERS AND COMMERCIAL
ESTABLISHMENTS

TO TAKE SAMPLES

QUALITY ANALYSIS

HEALTH LICENSE

A LEGAL PERMIT GRANTED BY THE INVIMA,
AUTHORIZING A NATURAL OR LEGAL ENTITY
TO:

- MANUFACTURE, IMPORT MARKET, EXPORT
- PACK, PROCESS OR SELL

A PRODUCT CONTROLLED BY THE INVIMA

TYPES OF HEALTH LICENSES

MANUFACTURE AND SELL

IMPORT RAW MATERIAL, MANUFACTURE AND SELL

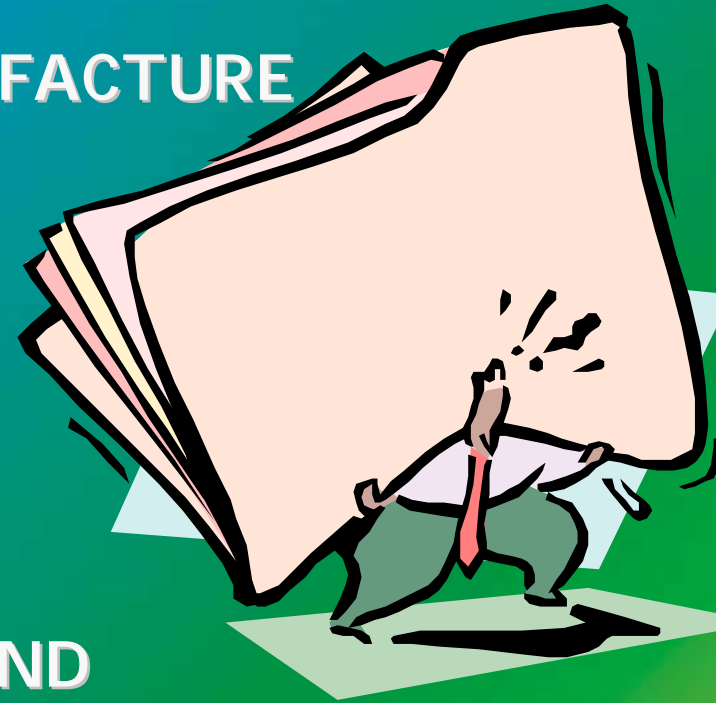
IMPORT AND SELL

IMPORT, PACK AND SELL

FILL AND/OR PACK

IMPORT, PARTIALLY PROCESS AND SELL

MANUFACTURE AND EXPORT



NO-TALS-GEL

- LAW 9,1979- NATIONAL SANITARY CODE
- DECREE 2092,1986 (MEDICAL AND SURGICAL DEVICES)
- RESOLUTIONS FROM REVISORY COMMITTEE AND MINISTRY OF HEALTH
- TECHNICAL REGULATIONS



NEW DECREE

INVIMA

NEW DECREE AND APPLICATION SCOPE

The Decree Includes:

- All sanitary Registration Modalities
- Quality Control and Sanitary Surveillance Programs
- Production, Processing, Packaging, Use
- Import, Export
- Storage and Commercialization of Medical Devices.

NEW DECREE

**HEALTH LICENSE
AND SURVEILLANCE
DISPOSITIONS**

ANNEX

QUALITY SYSTEM BASED ON:

**GUIDANCE ON QUALITY SYSTEMS FOR THE DESIGN
AND MANUFACTURE OF MEDICAL DEVICES" -
GHTF STUDY GROUP 3**

DECREE 2092 DE 1986

ONLY EQUIPMENT USED FOR APPLICATION OF DRUGS AND SIMILAR (MEDICAL AND SURGICAL DEVICES)

LIST OF DEVICES REQUIRING REGISTRATION

REGISTRATION REQUIREMENTS FOR THE LISTED DEVICES

NO GMP REQUIRED. ONLY HYGIENIC, TECHNICAL, QUALITY CONDITIONS MANUFACTURING FACILITIES

NO NOTIFICATION

NEW DECREE

ALL MEDICAL DEVICES

RISK BASE CLASSIFICATION

HEALTH LICENSEREQUIREMENTS ACCORDING TO THE CLASSIFICATION

GMP COMPLIANCE FOR MANUFACTURING PLANTS

NOTIFICATION OF ADVERSE EVENTS

INTERNATIONAL WORKSHOP ON MEDICAL DEVICES REGULATIONS - ANDEAN REGION

CARTAGENA, COLOMBIA, 2001

- . US-FDA
- . MEDICAL DEVICES BUREAU - HEALTH CANADA
- . ANMAT - ARGENTINA
- . PAHO
- . ECRI
- . GHTF

COUNTRIES

- . COLOMBIA
- . CHILE
- .. VENEZUELA
- . PERU
- . ECUADOR
- . PANAMA (OBSERVER)

REFERENCED DOCUMENTS CONSULTED FOR THE PROPOSED DECREE AND THE ANNEX RELATED TO THE QUALITY SYSTEM FOR MEDICAL DEVICES

TRANSLATE TO SPANISH - GHTF DOCUMENTS

1. Essential Principles Of Safety & Performance of Medical Devices
2. Role of Standards in the Assessment of Medical Devices
3. Labelling For Medical Devices
4. Information Document Concerning Definition of the Term "Medical Device"

CONTINUE TRANSLATE TO SPANISH - GHTF DOCUMENTS

5. Medical Devices Classification
6. Medical Devices: Post Market Surveillance National Competent Authority Report Exchange Criteria
7. Manufacturers Trend Reporting of Adverse Events



INVIMA'S WEBSITE

<http://www.invima.gov.co>

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THANK YOU !!!

Atardecer en el río Apaporis - Amazonas (Colombia).