# The Pharma Legal Handbook

# Nicaragua

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms

PHARMA BOARDROOM

# Nicaragua

**The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Nicaragua.
It is a must have for any company operating in the country or looking to enter the market.**

**Prepared in association with Bendaña & Bendaña, a leading Nicaraguan law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.**



*** THIS REPORT WAS ORIGINALLY PUBLISHED IN FEBRUARY 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

Bendaña & Bendaña
Abogados

Even though the Bendaña family legal tradition goes back to the last decade of the 19th century, Bendaña & Bendaña has its origin in the incorporation in 1950 of our founder and Director, Dr. Julián Bendaña-Silva, to the Law Firm of Dr. Vicente Navas Arana, his friend, colleague and former University Professor. Dr. Julián Bendaña Silva had graduated in 1948 with a Doctorate in Law from Universidad Nacional de Nicaragua and Dr. Navas Arana (1900-1985) was one of the most prominent attorneys in Nicaragua.

At Bendaña & Bendaña our objective is to combine our experience and legal tradition with innovation. As a result, we aim toward the efficient use of information technology and our members keep abreast of the latest developments in the field of Law. Bendaña & Bendaña's experience and tradition have been built up over 65 years of practice.

Areas of practice:
Intellectual Property Law. Registration, advise, contract writing and revision in all areas of Intellectual Property Law, including Trademarks, Patents, copyrights, Trade Secrets and Internet Law.

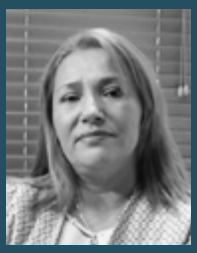
Regulatory Affairs. General regulatory issues, including marketing authorization of pharmaceutical, food, cosmetic, chemical, and veterinary goods.

Real Estate Law. Real Estate due diligence, appraisals, surveys and inspections. Drafting of Mortgages, Deeds, Purchase/Sale Contracts (closings) and Promissory Contracts.
Corporate and Commercial Law. Business contracts, contract writing, breach of contracts, establishment of Nicaraguan corporations, tax and financial advice.

Immigration Law. Nicaraguan residency for foreign investors and other immigration issues.
Our team of professionals is devoted to providing efficient and quality service to our clients, by protecting and defending their interests with fidelity and professional ethics.

The clients of the firm range from large international corporations from very diverse industries to small and medium size domestic businesses.

# THE AUTHORS



## GABRIELA YESENIA ZELAYA MOJICA

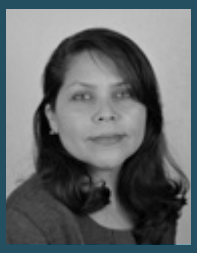
While studying her professional career as a Pharmaceutical Chemist, Ms. Gabriela Yesenia Zelaya Mojica has been working for the firm Bendaña & Bendaña in the field of Regulatory Affairs since 1996 and as Head of the department since 2014.

Additionally, Ms. Zelaya Mojica obtained her Bachelor's Degree in Pharmaceutical Chemistry at the University Jean Jacques Rousseau "UNIJJAR" in Managua, Nicaragua, where she studied from January 2010 to July 2014.

During these years in which she has worked in the Chemical-Pharmaceutical field, she has acquired empirical experience and later reinforced her knowledge through her academic preparation, participating in courses, seminars and trainings that have enriched her professional knowledge.

Throughout Ms. Zelaya Mojica's 28-year career in Regulatory Affairs, she has assisted clients in the pharmaceuticals, food, veterinary and pesticides industries in navigating the often times bureaucratic registration processes at government institutions and the Ministry of Health in Nicaragua. She has also helped many clients overcome seemingly insurmountable hurdles to obtain the necessary licenses and permits to market their goods in Nicaragua.

In recent years, Ms. Zelaya has also headed several region-wide projects, handling the registration procedures for several brands in all of Central America, while coordinating with local counsel.



## MARÍA JOSÉ JIRÓN-BENDAÑA

Ms. María José Jirón-Bendaña is a senior attorney at Bendaña & Bendaña. She has over 15 years of experience in trademark and patent matters in Nicaragua, as well as the Central American region. She was part of the team responsible for setting up additional offices for Bendaña & Bendaña in Guatemala, El Salvador, Honduras, Costa Rica and Panama. She also liaises with the firm's correspondent office in Cuba, and has worked closely with attorneys in the United States on various Intellectual Property projects. Bendaña & Bendaña currently offers full Intellectual Property services in all of these countries, in addition to Nicaragua.

Besides having a Bachelor's of Law from Universidad American (UAM) in Managua, Nicaragua, Ms. Jirón-Bendaña has a Bachelor's degree in Business Administration from Miami International University, as well as a Master's in Business Administration from the same institution. She is also licensed as a Title Insurance Agent in the State of Florida, which enables her to transact real estate closings in that state.

Ms. Jirón-Bendaña's area of expertise includes patent and trademark prosecution across the Central American region and Cuba. This experience has enabled her to take on multi-country projects in Latin America, not only for filings but also for the prosecution of oppositions and infringement actions.

# THE AUTHORS

## RICARDO J. BENDAÑA-GUERRERO

Ricardo J. Bendaña-Guerrero holds degrees in Engineering and Law, as well as a master's degree in Intellectual Property Law. In 1986 he obtained his engineering degree from Florida International University. After working as an engineer for several years, he decided to join his father's law firm, Bendaña & Bendaña, for which purpose, he pursued a law degree in Nicaragua from Universidad Americana (Managua, Nicaragua), which he obtained in 1998, and subsequently incorporated as an Attorney with the Nicaraguan Supreme Court in 1999. Mr. Bendaña obtained his Master of Laws from the University of Alicante in Spain in 1999. His master's degree, of over 600 hours of face-to-face classes, centered around patents of invention, trademarks, designs and copyrights. In order to be awarded the degree, he successfully defended a thesis entitled Comparison of Word Marks Involving Elements Lacking Distinctiveness before an international jury, in which he critically analyzed several judgments of the Nicaraguan Supreme Court. Later, with additional materials, he published his thesis as a book.

Throughout his professional life, Mr. Bendaña has been closely involved in trademark and patent prosecution, enforcement and litigation. Mr. Bendaña routinely oversees the response to office actions to patent applications issued by the Patent Offices in Nicaragua, Guatemala, El Salvador, Honduras and Costa Rica, as well as the response to office actions and oppositions to trademark applications in Nicaragua and other Central American countries. In addition, he oversees the drafting and submission of oppositions to trademark applications by third parties in Nicaraguan and other Central American countries. He has successfully participated in numerous lawsuits related to trademark and patent infringement, in which he has obtained the seizure of infringing goods, and subsequently the declaration in a judgment that the infringement took place. He also has participated in proceedings before the Nicaraguan Supreme Court in cases involving trademarks and patents.

As part of his work, Mr. Bendaña routinely deals with a variety of clients, including individuals, multi-national, national, and local companies involved in many different industries, including pharmaceutical, foodstuffs, agricultural, financial services, beverage, manufacturing, etc.

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15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

# 01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

**1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?**

Ministry of Health, in the following departments:

- Pharmacy Management
- National Laboratory
- Directorate of Sanitary Regulation (medical devices) - **Exhibit 1**

**2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?**

- Central American Technical Regulations
- Law on Drugs and Pharmacies, Law No. 292.
- Regulation of Law No.292, Law on Drugs and Pharmacies
- Standard for the Registry of Medical Devices, Regulations - 064

**3. What are the steps to obtaining authorization to develop, test, and market a product?**

We enclose the steps to follow - **Exhibit 2** / Requirements – **Exhibit 3**

**4. What are the approximate fees for each authorization?**

HEALTH RECORDS OF MEDICATIONS:

- Official expenses - US $ 485.10 - These costs are increased at the time of performing the analysis for each product, depending on the number of batches to be imported.
- Miscellaneous expenses - US $ 50.00
- Fees and taxes - US $ 300.00

BIOLOGICAL PRODUCTS:

- Official expenses - US $ 485.10 - These costs are increased at the time of performing the analysis for each product, depending on the number of batches to be imported.
- Miscellaneous expenses - US $ 50.00
- Fees and taxes - US $ 300.00

MEDICAL DEVICES PRODUCTS:

- Official Expenses - US $ 300.00
- Variable expenses - US $ 100.00
- Fees - US $ 500.00

| | |
|---|---|
| **5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?** | It has a validity of 5 years.<br>Renewal process: renewal is carried out 3 months before its expiration.<br>See the final section: **Exhibit 4**, for more information. |
| **6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?** | The authorization process is the same for branded and generic products. |
| **7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?** | In Nicaragua, only drugs + drugs are regulated, but drug + biological, drug + device, biological + device, drug + biological + device are combinations that are not regulated. |
| **8. How is compliance with regulations monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?** | It is regulated by the Central American Technical Regulation that is only used at a Central American level. It is not equal to the regulatory regime of the US Food and Drug Administration, nor is equal to the expectations and requirements of the European Medicines Agency. |
| **9. What is the potential range of penalties for noncompliance?** | According to Law 292, Law on medicines and pharmacies, it is declared in the following articles:<br>**Article 96.-** Any natural or juridical person that infringes this Law and its complementary regulations will be sanctioned administratively by the authorities of the Ministry of Health, without prejudice to the criminal and civil responsibility of which it could be object.<br><br>**Article 97.-** For the purposes of this Law, infractions shall be classified as minor, serious and very serious according to the criteria of health risks, amount of the eventual benefit obtained, degree of intentionality, severity of the sanitary and social alteration produced , generalization of the infraction and recidivism.<br><br>**Article 98.-** Minor infractions are the following conducts:<br>**(a)** The modification by any of the conditions on the basis of which the authorization of the establishment was granted when there is no risk to the health of the population;<br>**(b)** Failure to comply with the reports addressed to the Ministry of Health;<br>**(c)** The lack of pharmacopoeias and basic lists in establishments;<br>**(d)** Difficulty the work of pharmaceutical inspectors;<br>**(e)** Dispense medications when the expiration date of the prescription has expired; |