



# BOIRON BRAND QUALITY GUIDELINES

## INTRODUCTION

Boiron USA is committed to supporting the sales of our products through our brand advertising, trade promotions, and consumer education. Boiron strives to be a leader in its field of product quality for the benefit of its customers. Boiron has adopted the following Brand Quality Guidelines as a condition for the sale and offer for sale of Boiron products. Boiron's goal in establishing this policy is to avoid degradation of, or damage to, the premium quality of its products and to the trademarks, brands, trade names and other marks under which its Boiron products are sold.

These guidelines are unilaterally created and implemented by Boiron. Boiron will not invite or accept any input into how the guidelines will be administered or maintained. These guidelines do not reflect or constitute an agreement between Boiron and any authorized distributor, reseller, any other person or entity. By issuing these guidelines, Boiron is not seeking any agreement from any entity.

## GENERAL GUIDELINES

It is essential that all distributors, resellers and others in the Boiron distribution network adhere to the following terms and conditions. Failure to abide by these terms and conditions may result in the penalties set forth herein.

1. The Brand Quality Guidelines and MAP Policy apply to all Boiron products, except as may be designated by Boiron from time to time. The MAP prices for the products can be found on Boiron's website at <https://www.boironusa.com/retailers/qmapp/>. Boiron may in its sole discretion update or modify this list from time to time. The applicable quality regulations for the products are listed in Appendix A.
2. Boiron recognizes that distributors and resellers are free to make their own decisions to advertise and sell any Boiron product at any price they choose, without consulting or advising Boiron, subject to the terms of these guidelines.
3. The guidelines apply to advertised prices, not the price at which MAP products are actually sold or offered for sale to an individual in-store, over the telephone or on the internet.
4. Boiron will make its own decisions regarding the Boiron Authorized Reseller Program, supplemental marketing materials, point-of-purchase displays, product allocation, new product availability, or future promotional, joint marketing, or sponsorship programs.
5. Resellers, distributors and others in the Boiron distribution network are required to comply with all applicable laws. Among other things, all shipments to California are subject to the requirements set forth in Proposition 65, which requires business to provide certain warnings.

## QUALITY STANDARDS

Boiron manufactures and sells homeopathic products in compliance with industry and regulatory standards. The storage, sale, shipping, and handling of all Boiron products must

comply with all quality standards Boiron issues from time to time and all applicable laws and regulations. Any deviation from these standards is a violation of these guidelines.

**Application of MAP Standards**

The MAP standards apply to any and all advertisements for any Boiron product in any and all forms of print and electronic media, direct mail, and audio and video communications. For clarity, the MAP standards apply to all coupons, coupon and promotion codes, flyers, inserts, magazines and circulars, mail order catalogs, mailers, postcards, newsletters, newspapers, posters, billboards, television advertising, radio advertising. The MAP standards also apply to all internet-based advertising, including for example, all e-mail solicitations, website advertising, banner ads, click-throughs, social media advertisements and other forms of internet advertising, which may be identified in the future.

**ADVERTISING MINIMUM PRICES**

1. The MAP standards apply to advertised prices of Boiron products, and not the prices at which Boiron products are actually sold. Resellers and distributors are free to resell Boiron products at any price of their choice.
2. The minimum advertised price for each Boiron product shall be the price designated as the MAP on the MAP policy. If no MAP is listed for any Boiron product, the MAP will be the Manufacturer’s Suggested Retail Price (“MSRP”) for that product minus 10% of that MSRP. (Current price lists may be obtained by contacting a Boiron sales representative.)
3. Boiron considers any price advertised below the MAP a violation of its Brand Quality Guidelines. For example, if a product with a MAP of \$9.95 is advertised below \$9.95, it is a violation of these guidelines.
4. Subject to the “Modification of Policy” terms below, advertising prices (especially on the Internet) includes all methods of displaying prices or any reference to higher discounting for any Boiron product, together with a picture or a description of such product. Examples of advertising violations include but are not limited to the following:
  - a. The use of a rebate, coupon, promotion, volume discount, rewards program, giveaway, or incentive that reduces the advertised price below the minimum advertised price;
  - b. Offering free shipping and handling of Boiron products if the monetary value for such offer results in the display of the price for such product below the established minimum advertised price;
  - c. Any strike-through or other alteration of the established minimum advertised price;
  - d. The use of “click on” or “click through” buttons on a website, or any similar buttons or automated price quotation transmission features, to provide automatic price quotations at or below the established minimum advertised price;
  - e. Language such as “Click ‘Buy’ for Price” or “Click ‘Add to Cart’ for Price” or “Click for Quote” if used on the same website page on which Boiron products are being advertised for sale and where such language results in a price offered lower than the minimum advertised price and/or are used in a way that confuses or misleads consumers; and
  - f. Statements such as “Click here for Lower Price,” “Add to Cart for Lower Price,” or “Check Cart for Lower Price” where such language results in a price offered lower than the minimum advertised price and/or are used in a way that confuses or misleads consumers.

**ADVERTISING BUNDLES**

1. Advertising two or more Boiron products for sale together at a price less than the combined MAPs for each Boiron product is a violation of these guidelines. For example, if a Boiron product bundle includes one Boiron product with a MAP of \$9.95 and a second

Boiron product with a MAP of \$7.95, any advertisement below \$17.90 (the combined MAP of the products) would violate the MAP policy.

2. The inclusion in advertising of free or discounted products with a product covered by this policy violates this policy if it has the effect of discounting the advertised price of the Boiron product below the minimum advertised price.
3. Advertisements featuring a Boiron product along with another brand of product will violate these guidelines if the price in the advertisement is lower than the Boiron product's MAP. In determining whether the advertisement contains a price in compliance with the MAP policy, Boiron will assess whether a reasonable viewer of the ad will, looking within the four corners of the advertisement, conclude that the ad is stating a price for the Boiron product below the MAP.
4. It is a violation of these guidelines to create, copy, print, assign or otherwise generate a UPC or barcode for any Boiron product, including without limitation creating a UPC or barcode for a bundle of products that includes a Boiron product.

### **LIMITATIONS ON CERTAIN E-COMMERCE SITES**

In the event a reseller, distributor or other entity in the Boiron distribution network sells a Boiron product through any third-party, unauthorized or fraudulent website or a site that has the likelihood of adversely impacting any Boiron brand, Boiron may impose any of the enforcement mechanisms set forth below. And, any sales of any Boiron products sold through such sites are void of any corporate warranties, obligations or guarantees.

### **MODIFICATIONS TO POLICY**

1. Boiron reserves the right to modify, suspend, or cancel the Boiron Brand Quality Guidelines and MAP policy, or modify any or all MAPs at any time. Boiron will provide notice of any such modifications, suspension or cancellations on the designated Boiron website. All resellers, distributors and other members of the Boiron distribution network are required to monitor the Boiron website for updates.
2. MAP for one or more products may be amended from time to time and may be suspended periodically for national, regional and/or seasonal promotions sponsored by Boiron. Boiron may also modify MAP for any Boiron product bundles.
3. If a distributor or reseller with multiple store locations violates the Boiron Brand Quality Guidelines and MAP policy at any one store location, or on any one website, then Boiron will consider this to be a violation of the distributor or reseller for all locations and websites.
4. Although the Boiron Brand Quality Guidelines and MAP policy do not contemplate any special promotions or events created or implemented by a distributor or resellers, Boiron may work with a reseller, distributor or other entity to create or implement such a promotion.
5. Boiron sales, marketing, or other personnel are not authorized to modify or grant exceptions to the Boiron Brand Quality Guidelines and MAP policy; provided however the VP of Sales or Ecommerce Director may approve modifications to this policy for a particular circumstance.

### **Enforcement**

If a distributor, reseller or other member of the Boiron distribution network advertises prices below those required by the Boiron Brand Quality Guidelines and MAP policy or violates any of the quality standards set forth herein, Boiron may, in its sole discretion, impose sanctions, including but not limited to one or more of the following actions:

1. Notify the violator of the non-compliant advertisement or quality standard with a reminder of Boiron's Brand Quality Guidelines and MAP policy on Boiron products;
2. Cancel any pending orders;

3. Suspend the violator's right to sell a portion of the Boiron product portfolio for a period of time (e.g., thirty (30), forty-five (45), ninety (90) days or longer) depending on the breadth and severity of the Boiron Brand Quality Guidelines and MAP policy violation, commencing from the date of notice from Boiron;
4. Suspend the violator's right to sell the entire Boiron product portfolio for a period of time (e.g., thirty (30), forty-five (45), ninety (90) days, or longer) depending on the breadth and severity of the Boiron Brand Quality Guidelines and MAP policy violation, commencing from the date of notice from Boiron;
5. Terminate the right for a distributor, reseller or other entity to sell or offer for sale any Boiron product;
6. Terminate the distributor/reseller agreement or other relationship between Boiron and the violator; and/or
7. Notify local, state, or federal authorities of any violations of the law.
8. Notify any marketplace or platform owners, operators or stakeholders, including as applicable Amazon.com, Walmart.com and others.

Boiron will make all decisions concerning compliance with and enforcement of the Brand Quality Guidelines and MAP policy in its sole discretion. Boiron will not be held liable or responsible in any way for any actions or inactions (such as fees or shipment costs from canceled or delayed orders) that occur as a result of the suspension, termination or any other penalty imposed herein. Further, Boiron shall not have any obligation to pay for any returned products by way of a refund or credit or otherwise.

#### **NOTICE AND CURE**

Boiron will notify the distributor, reseller or other entity within the Boiron distribution network of any violation of this policy. In the event Boiron permits the violator to correct such violation, prior to suspension, termination, cancellation or other enforcement action, the violator shall correct the violation to Boiron's satisfaction within the time period set forth in written notice (the "Cure Period"). Failure to correct such violation within the Cure Period shall result in a subsequent violation. Violations shall continue to multiply for each twenty-four (24) period in which the violation is not corrected. Each repeat violation during the twelve (12) month period following any initial or subsequent violation may result in Boiron taking any of the enforcement measures described above.

Should you have any questions about Boiron's Brand Quality Guidelines and MAP policy, please direct them to [qualityandmap@boiron.com](mailto:qualityandmap@boiron.com)

**APPENDIX A**  
**QUALITY STANDARDS**

Boiron's quality standards are set forth below:

<b>Boiron Requirement</b>	<b>CFR Reference</b>	<b>FDA Requirement</b>
Persons responsible for holding and distribution of drug products must have appropriate training, education and/or experience.	21 CFR 211.25	Subpart B--Organization and Personnel. Sec. 211.25 Personnel qualifications. (a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions.
Product must be stored in a climate-controlled warehouse between temperatures of 68-77°F (20-25°C)	21 CFR 211.46, 21 CFR 211.142	Subpart C--Buildings and Facilities. Sec. 211.46 Ventilation, air filtration, air heating and cooling. (b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product. Subpart H--Holding and Distribution. Sec. 211.142 Warehousing procedures. Written procedures describing the warehousing of drug products shall be established and followed. They shall include: (a) Quarantine of drug products before release by the quality control unit. (b) Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected. 21 U.S. Code § 351. Adulterated drugs - A drug or device shall be deemed to be adulterated— (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture. 21 U.S. Code § 331 Prohibited Acts. The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce any food, drug, device tobacco product, or cosmetic that is adulterated or misbranded.
Product must not be stored with poisonous chemicals	21 CFR 211.46	Subpart C--Buildings and Facilities. Sec. 211.42 Design and construction features. (b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. 21 U.S. Code § 351. Adulterated drugs - A drug or device shall be deemed to be adulterated— (a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture. 21 U.S. Code § 331 Prohibited Acts - The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce any food, drug, device tobacco product, or cosmetic that is adulterated or misbranded.
Cannot be shipped with poisonous chemicals	21 CFR 211.46	Subpart C--Buildings and Facilities. Sec. 211.42 Design and construction features. (b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination.
Lot control	21 CFR 211.150, 21 CFR 211.196	Subpart H--Holding and Distribution. Sec. 211.150 Distribution procedures. Written procedures shall be established, and followed, describing the distribution of drug products. They shall include: (a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate. (b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary. Subpart J--Records and Reports. Sec. 211.196 Distribution records. Distribution records shall contain the name and strength of the product and description of the dosage form, name and address of the consignee, date and quantity shipped, and lot or control number of the drug product. For compressed medical gas products, distribution records are not required to contain lot or control numbers.
Expiration date control	21 CFR 211.150	Subpart H--Holding and Distribution. Sec. 211.150 Distribution procedures. Written procedures shall be established, and followed, describing the distribution of drug products. They shall include: (a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is

		temporary and appropriate. (b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.
Must maintain distribution records	21 CFR 211.150	Subpart H--Holding and Distribution. Sec. 211.150 Distribution procedures. Written procedures shall be established, and followed, describing the distribution of drug products. They shall include: (a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate. (b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.
System for taking in, managing and reporting quality problems and adverse events associated with the products.	21 CFR 211.198	Subpart J--Records and Reports. Sec. 211.198 Complaint files. (a) Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with 211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with 310.305 and 514.80 of this chapter.
System to manage returned merchandise	21 CFR 211.204	Subpart K--Returned and Salvaged Drug Products. Sec. 211.204 Returned drug products. Returned drug products shall be identified as such and held. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product shall be destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity.
Can not resell damaged or open merchandise	21 CFR 211.204	Subpart K--Returned and Salvaged Drug Products. Sec. 211.204 Returned drug products. Returned drug products shall be identified as such and held. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product shall be destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity.
Can not resell merchandise rejected by Boiron or any other retailer	21 CFR 211.208	Subpart K--Returned and Salvaged Drug Products. Sec. 211.208 Drug product salvaging. Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall not be salvaged and returned to the marketplace.
Can not repackage Boiron products.	21 CFR 201.6, 21 CFR 207.17, 21 CFR 211.122 through 211.137	Subpart A--General Labeling Provisions. Sec. 201.6 Drugs; misleading statements. (a) Among representations in the labeling of a drug which render such drug misbranded is a false or misleading representation with respect to another drug or a device or a food or cosmetic. Subpart G--Packaging and Labeling Control. 211.122 through 211.137 apply to packaging operations. Packagers are to be registered with the FDA per Subpart B--Registration. Sec. 207.17 Who must register? (a) Unless exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or this part, all manufacturers, repackers, relabelers, and salvagers must register each domestic establishment that manufactures, repacks, relabels, or salvages a drug. 21 U.S. Code § 352. Misbranded drugs- A drug or device shall be deemed to be misbranded—(a) False or misleading label(1)If its labeling is false or misleading in any particular. 21 U.S. Code § 331 Prohibited Acts The following acts and the causing thereof are prohibited: (a) The introduction or delivery for introduction into interstate commerce any food, drug, device tobacco product, or cosmetic that is adulterated or misbranded.
Boiron products with prescription indications may only be sold to, marketed by, and distributed by properly	21 CFR 203.50	Subpart E--Wholesale Distribution. Sec. 203.50 Requirements for wholesale distribution of prescription drugs. (d) List of authorized distributors of record. Each manufacturer shall maintain at the corporate offices a current written list of all authorized distributors of record.

licensed and identified entities.		
System to evaluate promotion, advertising and auxiliary labeling of the products to avoid risk of off label claims (misbranding).	21 CFR 201.6	Subpart A--General Labeling Provisions. Sec. 201.6 Drugs; misleading statements. (a) Among representations in the labeling of a drug which render such drug misbranded is a false or misleading representation with respect to another drug or a device or a food or cosmetic. 21 U.S. Code § 352. Misbranded drugs - A drug or device shall be deemed to be misbranded—(a) False or misleading label(1) If its labeling is false or misleading in any particular.
Meet State licensing requirements to all states distributed to.	See State Department of Health and/or State Board of Pharmacy	Requirements for drug distributor are defined by each individual state in which the distributor resides. Requirements are also defined by individual states for licensure and/or registration of all drug distributors selling drug products into the state.
Manage, collect and pay appropriate sales taxes.	See State Regulations	Requirements for drug distributor sales are defined by each individual state in which the distributor resides. Sales tax requirements are also defined by individual states for drug distributors selling drug products into the state.