BLAZE THERAPEUTICS

Responsible Distribution Compliance Manual

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Responsible Distribution Compliance Manual

This Responsible Distribution Compliance Manual (this "RD Manual") has been developed and adopted as a public corporate document of Blaze Therapeutics LLC and is protected by copyright law and thus shall be treated as the intellectual property of Blaze Therapeutics. This RD Manual may be amended by Blaze Therapeutics LLC as federal and state laws change, science and technology evolves, and the industry grows. Blaze Therapeutics LLC reserves the right to amend this RD Manual without any given advance notice to vendors, manufacturers, partners, customers, and/or affiliates.

Manufacturers must produce CBD and other products derived from hemp, as legally defined by the current U.S. laws. Current federal law dictates:

1. Any *Cannabis* plant or *Cannabis* derived product that contains more than 0.300 percent (%) delta-9 THC is considered marijuana under federal law, which is still classified as a controlled substance under federal law.
2. Section 12619 of the 2018 Farm Bill Act amends the Controlled Substances Act in two ways:
    a. It removes hemp from the definition of marijuana in section 102(16) of the Controlled Substances Act, 21 U.S.C. § 802(16).
    b. In listing THC as a Schedule I controlled substance in section 202(c) of the Controlled Substances Act, 21 U.S.C. § 812(c), it creates an exception for tetrahydrocannabinols in hemp.
3. Section 10113 of the 2018 Farm Bill provides that "the term 'hemp' means the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.300 percent on a dry weight basis."
4. On August 27, 2019, the DEA published a public letter recognizing the amendment by the Agriculture Improvement Act of 2018 (also known as the 2018 Farm Bill Act) to federal law removing hemp, as it is defined by the 2018 Farm Bill Act, as no longer requiring DEA registration to grow or manufacture. Accordingly, hemp, including hemp plants and cannabidiol (CBD) preparations at or below the 0.300 percent (%) delta-9 THC threshold, is not a controlled substance, and a DEA registration is not required to grow or research it.

All varieties of each product produced by the manufacturer must be traceable via batch/lot numbers. Subsequently, each batch/lot must correspond to a Certificate of Analysis (COA) made available by the manufacturer, brand owner and/or unbiased third party. In other words, each COA must indicate which batch/lot of product was tested; of which the corresponding batch/lot number must be printed on the final product's label and/or packaging.

Blaze Therapeutics will reject any products that do not meet the following specifications:

1. Product's label and its claims must be compliant for Responsible Distribution (RD), as dictated by the RD Manual.
2. Products' formulation must be therapeutically promising.
3. Product must be **unbiased** third-party laboratory tested.

Responsible Distribution

Responsible Distribution (RD) is a distribution model designed specifically for the healthcare industry, with precautions taken to protect for consumer safety. The RD model requires each product to undergo an evaluation for it's therapeutic potential and label claims for compliance. Once the product is identified as qualifying for Responsible Distribution, each batch/lot of product must undergo Unbiased Third Party Testing before distribution. All Responsibly Distributed CBD products are accompanied by a readily available unbiased third party COA. Responsibly Distributed products can be identified by the following Responsibly Distributed seal.

There are three types of Certificates of Analysis (COAs)

Outsourced Tested products (often referred to as "third party tested" on product packaging and descriptions) are sent to a "third party" laboratory for testing by the company that manufactures the finished product(s) and/or the brand owner. Unfortunately, the finished products that are sent to the laboratory by the manufacturer to be tested are not always the same finished products that get distributed to the public. Additionally, when a product fails laboratory testing, the manufacturer may still choose to distribute the failed batch/lot in an attempt to avoid the loss of funds that would otherwise be absorbed should the products be appropriately discarded. Often, these products are sold at a significantly reduced price to vendors who are strictly financially motivated.

In-house Tested products (often referred to as "lab tested" on packaging and product descriptions) are not sent to a "third party" laboratory and are instead tested, in-house, by the manufacturer and/or brand owner. These "lab tests" tend to be extremely limited and often do not test for toxin levels. If a manufacturer is sharing the laboratory results of an in-house tested product to consumers as a valid COA, vendors and consumers are strongly advised to avoid these CBD products for their high potential of being a risk to public health.

Unbiased Third Party Tested products (only referred to as "unbiased third party tested") are third party laboratory tests paid for by an unbiased company, that does not possess any conflicts of interest to affect its unbiased position. In order for a company to qualify as an unbiased 3rd party, the company cannot have any financial interests in the product's brand. Blaze Therapeutics is currently the only unbiased 3rd party company with an unbiased third party testing program for manufacturers of holistic, plant-based, products.

Unbiased Third Party Laboratory Testing

For a product to be Unbiased Third Party Tested, one sealed final product (no samples are allowed) from each batch/lot must undergo laboratory testing at an ISO certified laboratory. The final product must be provided to the laboratory by an unbiased 3rd party company, of which the final COA is delivered to. This process ensures that the product meets label claims and does not contain harmful levels of heavy metals, pesticides, residual solvents, etc. The unbiased third party COA for each batch/lot number of product must meet the requirements as set forth by the Unbiased Third Party Service Manual.

Blaze Therapeutics is offering CBD manufacturers an affordable opportunity to enroll in the unbiased third party testing program for their products! The products do not need to qualify for Responsible Distribution in order to enroll into the unbiased third party laboratory testing program.

For further information on enrolling your products into the Unbiased Third Party Tested program, contact us via info@blazetherapeutics.com or 833-422-5293.

Get Responsible.

Responsible Distribution Compliance [Mandatory]

- **FDA Statement:** The following FDA statement must be printed legibly on all products derived from *Cannabis* and must not have any claims that contradict the statement:

  This product has not been evaluated by the FDA and is not intended to diagnose, treat, cure or prevent any disease or medical condition.

- **Total Cannabinoid(s) Concentration:** The total cannabinoid(s) concentration present in the entire container must be printed on the label in milligrams (mg).
- **Size of Container:** The size of the container must be printed on the label in milliliters (mL) and ounces (oz).
- **Batch/Lot Number:** The batch and/or lot number MUST be printed on the label in a manner that cannot be easily removed. The batch/lot number is the only way to ensure the product can be recalled should any issues arise. It is also the only way to identify the product in hand corresponds to the Certificate of Analysis (COA) provided by laboratories.
- **Dosage Guidance:** Because of cannabinoids' chemical nature, dosage guidelines cannot be generalized to each individual consumer. A dosage label pull out or an external card with dosage guidance should be made available so that the consumer can track and customize their daily serving by their unique individual body weight class and/or the following dosage statement should be printed:

  For dosage guidelines, please consult with your doctor and/or other qualified healthcare professional.

- **Graduated Dropper (if applicable):** The dropper applicator needs to have measurement markers on it in order to allow for accuracy and flexibility of serving sizes.
- **Ingredients:** The product's ingredients should be easily identifiable on the label and listed in order from greatest to least in concentration. Any product containing menthol, methyl salicylate, capsaicin or any other Over-The-Counter (OTC) ingredient(s) must be accompanied by the concentration in percentage (i.e. Menthol 1%).
- **Allergy Warning:** Any applicable allergy warning must be listed after the ingredients (e.g. may contain tree nuts, soy, shellfish, etc.).

Disqualification Factors

- "Dietary Supplement" printed anywhere on packaging.
- The inclusion of any "flavor" in the product's ingredients. This includes "natural flavor". Fruit and vegetable extracts are allowed.
- The inclusion of high fructose corn syrup and/or artificial sweeteners (i.e. sucralose, aspartame, and saccharine) in the product's ingredients. The type of "sugar" included in the product, if applicable, must be identified (i.e. cane sugar, white sugar, brown sugar, etc.).
- The inclusion of any "artificial color" in the product's ingredients. Fruit and vegetable extracts used for coloring are allowed.
- The inclusion of sodium nitrites, nitrates, monosodium glutamate (MSG), butylated hydroxyanisole (BHA), and/or butylated hydroxytoluene (BHT).
- The inclusion of the term "terpenes" in the ingredient list without clarification as to the exact terpene that was added to the product's formulation.

Additional Guidelines for Quality CBD Products [Not Mandatory]

- **Product Dating:** Product dating for CBD products is based on stability of product's formulation and other ingredients.
  - An Expiration (EXP) date is a safety date and indicates to consumers the last day a product is safe to consume.
  - A Use-By or Best if Used By/Before date indicates when a product will be of best flavor or quality. It may just lose its freshness, taste, aroma or nutrients. It does not necessarily mean that the food is no longer safe to consume.
  - A Born On date is the date that the product was bottled and/or placed into it's packaging.
- **QR Code:** A QR code when scanned by a mobile device should link directly to the corresponding Certificate of Analysis (COA) for that specific product. NOTE: The QR Code is not a replacement for printing the batch/lot numbers on the product's label.
- **Location of Batch/Lot Number:** While the inclusion of the batch/lot number is mandatory for a product to qualify for Responsible Distribution, the location of the batch/lot number should be next to the QR code, if applicable. If a QR code is not included on the labeling, it should be printed on the side of the packaging that displays the list of ingredients.
- **UV Resistant Packaging:** The packaging for products like CBD is extremely important in the stability of the formulation. Given that CBD degrades when exposed to UV light, UV resistant packaging extends the shelf life of the product significantly. NOTE: While UV resistant packaging is tinted in appearance, a tinted container does not automatically make the packaging UV resistant.
- **GS1 Prefix & UPC Barcode:** A Universal Product Code (UPC) is a type of barcode that appears on packages as black lines of varying widths above a series of numbers. They are not required by regulation, but manufacturers print them on most product labels because scanners at stores can read them quickly to record the price at checkout. NOTE: The UPC is not used to identify recalled products.

NOTE

Each batch/lot of a Responsibly Distributed product must undergo Unbiased Third Party Testing.

To expedite the process of entering new CBD products into the Blaze Therapeutics wholesale network, manufacturers are welcome to enroll products into the Blaze Therapeutics Unbiased Third Party Testing program.

TINCTURES (Sublingual Drops)

Tinctures are liquid extracts made from herbs that you take sublingually (under the tongue). Tinctures are easy to dose and are best if taken directly under the tongue. Attention! Tinctures are NOT formulated for vaping. Given the rate of decomposition and average bioavailability of CBD extract formulations, tinctures less than 1000mg of CBD for human consumption and less than 750mg of CBD for animal consumption are not financially feasible for those seeking therapeutic effects.

VAPES

Vapes are e-liquids specially formulated to be heated up by an electronic device and vaporized. Vapes, if formulated and manufactured properly, can be fast acting and a potentially healthier alternative to smoking because of the absence of toxic substances otherwise present in smoke. Note: Vapes are NOT to be consumed orally as a tincture. Vapes are specifically formulated for consumption via inhalation. The temperature to which the formulated e-liquid can be safely heated to must be made apparent on the packaging. Overheating e-liquids above the temperature it has been formulated to can result in the development of toxic by-products that can result in lung injury. The product must also be labeled with the accurate form of cannabidiol, whether it is the neutral CBD form or the acidic CBDA form.

SPRAYS/AEROSOLS

An aerosol is a suspension of fine solid particles or liquid droplets, in air or another gas. Most commonly referred to as inhalers, aerosols can be fast acting and offer a more accurate method of dosing, when compared to vapes. Sprays are similar, but are not suspended in air or gas, but are formulated in a manner that allows for a consistent dose per spray.

EDIBLES

Edibles consist of various food-like formulations designed for oral consumption such as beverages, lozenges, gummies, and baked goods. Edibles tend to not be as fast acting as other oral, inhalation, and sublingual products, however the effects once initiated tend to be longer lasting, if the formulation is bioavailable. Edibles tend to be better tasting than other dosage forms and a preferred choice among younger individuals. Edibles can consist of ingredients that may be allergy inducing like tree nuts, soy, shellfish, etc. Edibles also tend to contain large amounts of sugar, which can result in unwanted side effects. Therefore, Blaze Therapeutics medical advisers review the ingredients and nutritional label of each product before acceptance.

CAPSULES & TABLETS

Oral capsules and tablets are traditional dosage forms whose bioavailability are dependent on carrier agents, as well as other inactive ingredients. Sublingual tablets tend to be more bioavailable than oral capsules and tablets. Capsules and tablets can consist of ingredients that may be allergy inducing like tree nuts, soy, shellfish, etc. and/or may be produced in a facility that processes allergens. All potential allergens must be printed on the label as per GMP standards. Blaze Therapeutics medical advisers review the ingredients and nutritional label of each product before acceptance.

TOPICALS

Topicals are designed for application to the surface of a part of the body and typically placed directly onto the skin. Topicals are great for facilitating rapid delivery of active ingredients to a specific location on the body. Topicals are great alternatives for any individual concerned about systemic side effects and/or drug interactions.

PATCHES

Patches are designed for application directly to the surface of the skin for a set period of time (typically 48 - 72 hours). Unlike topical applications, patches are great for facilitating extended release delivery of active ingredients systemically. Like with all of the other dosage forms listed, except for topicals, drug interactions must be considered when using patches.

SUPPOSITORIES

A suppository is a solid dosage form that is inserted into the rectum (rectal suppository), vagina (vaginal suppository), or urethra (urethral suppository), where it dissolves or melts and exerts local or systemic effects. Suppositories are used to deliver medications that act both systemically and locally. The type of suppository needs to be clearly defined, along with whether it is formulated for local or systemic effects.

The Process

1. Complete and submit the Distribution Application for any products you are requesting to be reviewed for Responsible Distribution: https://www.blazetherapeutics.com/distributionapplication
2. Each product will be reviewed for therapeutic potential, compliance, and market feasibility (a sample may be requested for specific product testing).
3. Upon the completion of the internal review, one of two purchasing agreements may be offered per product, depending on product's market performance potential:
    a. Invoice of all products ordered may be purchased directly after they clear unbiased third party laboratory testing in full.
    b. Products may enter distribution after clearing unbiased third party laboratory testing where payment is submitted to manufacturer on a consignment basis.
4. Blaze Therapeutics purchases on a per batch/lot basis. The type of payment process is established once the product is evaluated and qualifies for Responsible Distribution. If a product is chosen to be purchased on the basis of consignment, it is because we believe there is a strong possibility that the product may not sell as rapidly as other products, of which the reason is shared with the manufacturer for consideration. Each variety of product shipped to our facility must belong to the same batch/lot, unless the product is enrolled in the unbiased third party tested program. Blaze Therapeutics provides each manufacture with the opportunity to have all their products equally marketed to all of our wholesale vendors. For more information on our internal marketing program, email info@blazetherapeutics.com.