From: Angel piza <abad6000@gmail.com>
Sent: Thursday, June 23, 2022 5:35 PM
To: CCB Regulations
Subject: July 26 meeting comments

Any remediation processes should be made clear the the customer

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KIMBERLY MAXSON-RUSHTON
EMAIL: krushton@cooperlevenson.com

July 22, 2022

The Honorable Michael Douglas, Chair
Nevada Cannabis Compliance Board
700 E. Warm Springs Road, Suite 100
Las Vegas, NV 89119

Re: Nevada Cannabis Compliance Regulation 12.065

Dear Chair Douglas,

On behalf of RAD Source Technologies ("RAD") please allow this correspondence to serve as a request that the Cannabis Compliance Board's ("CCB") defer final consideration and adoption of proposed Nevada Cannabis Compliance Regulation ("NCCR") 12.065.

As the CCB is well aware, since December 2020, RAD has petitioned the Board to repeal NCCR 12.065 or amend the language to (i) ensure its applicability to all treatment processes used to ensure the growth and safety of cannabis products and, (ii) avoid imposing an unnecessary obligation on cultivators to include language on labels, which could be construed as a warning versus the assurance that the product has been treated for the consumer's health and safety.

In support of the request to repeal NCCR 12.065, RAD has provided the CCB with scientifically reliable information, including but not limited to two (2) studies, which demonstrate the safety and effectiveness of its process[1]. Moreover, in response to Staff's reliance on the U.S. Food and Drug Administration's ("FDA") labeling requirement (applicable to over the counter drugs treated using irradiation) RAD respectfully refers the CCB to the December 2020 filing, which contains notice of the FDA's decision to repeal said labeling requirement in 2019. See attached Exhibit 1.

RAD's request to repeal NCCR 12.065 is based on the volumes of scientific information submitted to the CCB and its predecessor, Marijuana Enforcement Division since 2019, which confirms that utilization of its process effectively eradicates harmful pathogens in cannabis (for the consumer's health and safety). Additionally, RAD seeks repeal of the regulation based on the comments made by members of the cannabis industry relative to the negative impact said labeling requirement will have on their business. Thus, the science behind RAD's currently approved

[1] The respective studies were previously submitted and requested to be maintained as "confidential." As such, complete copies are in the CCB's files however, RAD will gladly resubmit the studies at the CCB's request.

decontamination process coupled with the concerns articulated by members of the cannabis industry collectively demonstrate why the regulation is not necessary and otherwise overly burdensome.

As the CCB is aware, to date there have been multiple revisions to NCCR 12.065 submitted to the CCB for consideration, the latest of which was noticed in June 2022. See attached Exhibit 2. In response to the language currently proposed by Staff, RAD raises the following concerns for the CCB's attention: (i) the reference to ionizing irradiation; (ii) the applicability only to "post harvest" processes; (iii) the newly proposed approval process; and (iv) the obligation to include the method of treatment on cannabis labels.

Alternatively, in an effort to address these issues RAD submits the language proposed in attached Exhibit 3. Specifically, RAD's proposed language applies only to cannabis and cannabis products which have been remediated and it removes the term "ionizing irradiation." Consistent with the District Court's Order in the case filed by RAD in 2020, the CCB is prohibited from singling out one form of radiation. Please see attached Exhibit 4.

Correspondingly, the (limited) list of processes used within the cannabis industry to ensure a consumer's health and safety has been removed. As the CCB is aware, there are multiple processes used to grow / treat cannabis therefore, the language should be stricken or at a minimum, expanded to include all known processes. Similarly, the reference to post-harvest processes has been removed as it is lacks scientific support and arbitrarily focuses on only one part of the processes used by cultivators to produce safe and effective cannabis.

RAD submits that the language requiring Board approval of the process used by a cultivator to prevent contamination requires further rulemaking. Specifically, the creation of a new regulatory process / standard of approval warrants the promulgation of regulations detailing the regulatory standards for obtaining Board approval otherwise, the undefined standard is arbitrary and capricious.

Consistent with the request made by the cultivators that appeared before the CCB in March 2022, the label requirement has been removed. If it's determined that NCCR 12.065 is necessary RAD proposes that the regulation be applicable only to products, which have been remediated for the health and safety of the consumer and, that notification of the process used to remediate be included in the product packaging information. Thereby, providing a dispensary the ability to provide said information to a consumer upon request.

In conclusion, on behalf of RAD we'd like to thank the CCB for its continuing review and consideration of the concerns raised herein relative to NCCR 12.065.

Sincerely yours,

/s/ Kimberly Maxson-Rushton

Kimberly Maxson-Rushton, Esq.

cc: T. Klimas, Ex. Director, CCB

EXHIBIT “1”

EXHIBIT “1”

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FILE NO.

December 2, 2020

Hon. Michael Douglas, Chair
Nevada Cannabis Compliance Board
555 E. Washington Avenue, Ste. 4500
Las Vegas, NV 89155

Re: Petition to Request Repeal or Amendment of Nevada CCB Regulation 12.065

Dear Chair Douglas:

On behalf of RAD Source Technologies, Inc., please allow this correspondence to serve as a Petition requesting to repeal or, alternatively, amend Nevada Cannabis Compliance Board (CCB) Regulation 12.065 (also referred to as "Labeling Requirement"). This Petition is respectfully submitted pursuant to CCB Regulation 4.145.

A. Petitioner's name, business address and telephone number

Petitioner is RAD Source Technologies, Inc. (RAD Source), and its contact information is as follows:

RAD Source Technologies, Inc.
4907 Golden Parkway, Suite 400
Buford, GA 30518
954.873.2085

B. Basis of request to repeal or amend CCB Regulation 12.065

RAD Source requests that the subject regulation be repealed as it fails to articulate an agency rule, standard, directive or statement of general applicability which effectuates or interprets law or policy, or describes the organization, procedure or practice requirements of any agency. *See*, Nevada Revised Statute (NRS) 233B.038(1)(a). Instead, CCB Reg. 12.065 can be construed as being applicable *only* to cannabis decontaminated, post-harvest, using RAD Source's equipment, even though there are multiple forms of electromagnetic radiation used in and/or that come into contact with cannabis products throughout the entirety of the growth and production process. Sunlight, UV, overhead lights, grow lights, X-ray and radio frequency technologies are *all* forms of electromagnetic energy which expose cannabis to

radiation. However, the current regulation appears to target only post-harvest decontamination using ionizing radiation.

Furthermore, the regulatory warning is neither supported by scientific evidence nor was it promulgated by legislation. *See*, Senate Bill 533, 2019 Nevada Legislative Session. In fact, none of the statutory directives contained in NRS 678A.450, 678B.650 or 678C.490 speak to labeling standards or warning notices akin to that required in CCB Regulation 12.065; instead they evidence the Legislature's directives to the CCB to develop regulations pertaining to licensing, regulatory compliance, advertising, racial and gender equality and economic stability within the cannabis industry. Clearly, CCB Regulation 12.065 in no way furthers these legislative directives. However, as the CCB is aware, the Legislature did in fact promulgate specific labeling requirements for cannabis products, thereby evidencing a clear intent to identify exactly what information should be included on labels. *See*, NRS 678D.420. As the statutory language in NRS 678D.420 is clear and unambiguous RAD respectfully submits that CCB Regulation 12.065 neither effectuates nor interprets any law.

There are a limited number of methods used in the cannabis industry to decontaminate harvested flower. The use of ionizing radiation, in the form of X-rays, is one of those methods. The CCB has data clearly demonstrating that RAD Source's machines are a safe and effective method of preventing the development of mold, powdery mildew and *Aspergillus which can produce dangerous mycotoxins*. The Labeling Requirement contained in CCB Reg. 12.065 does nothing to make cannabis products any safer for consumers. It does, however suggest to the public that there may be something unsafe about the product they are purchasing, when the exact opposite is true. Without question, deterring consumers from purchasing safe products is counterproductive.

Equally concerning is the CCB mandated use of the Radura symbol on cannabis labels. As outlined in the attached U.S. Food and Drug Administration (FDA) Notice, the FDA has no concerns about over-the counter drugs sterilized with ionizing radiation, and therefore it does not require any labeling. Recognizing that cannabis is a drug, not food, in repealing the Labeling Requirement the CCB would be acting consistent with the FDA. The labeling mandates currently proposed by the CCB for cannabis are the current requirements from the FDA regulating the notice of use of ionizing radiation on eggs, beef, poultry and shellfish, none of which are cannabis.

C. Specific regulation in question:

> **12.065 Cannabis treated with radiation.** If any cannabis or cannabis product has been treated with radiation at any time, any and all packaging of the irradiated cannabis or cannabis product must include labeling that contains the following statement: "NOTICE: This product contains ingredients that have been treated with irradiation" in bold lettering, along with the Radura symbol as used by the U.S. Food and Drug Administration.

D. Requested amendment to or detailed statement as to why regulation should be repealed:

In support of the request to repeal CCB Reg. 12.065 RAD respectfully refers the CCB to the attached FDA Notice announcing the repeal of a regulation pertaining to irradiation of products used in over the counter (OTC) drugs. *See, 21 CFR Part 310* (Dec. 2019). As determined by the FDA, the technology for decontamination by irradiation is well known therefore, product labeling requirements are no longer necessary. More specific to the subject regulation is the FDA's determination that the repeal of the labeling requirement *would not diminish public health protections*.

Additionally, the CCB is in possession of scientific studies, data, and other reports and information, which clearly show that the use of ionizing radiation, and specifically the use of x-ray irradiation by a RAD Source machine, is a safe and effective method for decontamination of cannabis flower. This information includes the results of a safety study, *requested by CCB Staff from one of RAD Source's Nevada customers using RAD Source's equipment*, which conclusively demonstrates the safe use for decontamination of cannabis thereby demonstrating that CCB Reg. 12.065 is entirely unnecessary.
As evidenced by the findings stated in the FDA notice confirming that decontamination of a drug by irradiation poses no threat to the health and safety of the public, coupled with the plethora of scientific evidence previously submitted to the CCB on this specific subject, RAD Source respectfully requests that the CCB repeal Regulation 12.065. Alternatively, RAD Source requests that the CCB open a regulatory workshop for the purposes of amending the regulation. *NRS* 678A.460(1)(d).

Alternative CCB Regulation 12.065 language:

In the event the CCB disagrees that Regulation 12.065 should be repealed, RAD Source respectfully submits the following proposed language as an alternative to the currently adopted regulation:

> Each retail package of flower, which has been treated in any manner to reduce pathogens to a level below those set forth in NCCB Regulation 11.050 shall be labeled as follows:
> "***For your safety, post-harvest treatment of this product has been used to reduce pathogens potentially harmful to human health.***"
> (1) Treatments to reduce pathogen levels in cannabis include the use of:
> (a) chemicals, reactive oxygen
> (b) gas(es), ozone
> (c) photons, or electromagnetic waves
> (d) any other process steps taken during the cultivation process to bring the cannabis into compliance with the regulated pathogen level(s).

E. Statement identifying persons or groups who may be affected by the repeal of CCB Regulation 12.065 and the manner in which they will be affected:

Following multiple discussions with various members of Nevada's cannabis industry RAD Source submits that most, if not all, cultivators will be *positively impacted* by the repeal of CCB Regulation 12.065. Almost all cultivators use some form of post-harvest decontamination to treat cannabis in an effort to prevent mold or Aspergillus from developing post testing and while available to consumers. Thus, the regulation imposes a requirement which serves no purpose, is unnecessarily costly, requires additional space on each label and could deter consumers from using their product.

Similarly, dispensary operators will benefit from the repeal of CCB Reg. 12.065 as it creates an additional level of product review – verification of whether cannabis was treated by irradiation and if so, whether the label contains the proper NOTICE language. Furthermore, the regulatory NOTICE could create consumer concern that decontamination by radiation is unsafe - which is not accurate - and/or that certain cannabis strains are potentially dangerous when in reality the use of x-ray irradiation by a RAD Source machine is a safe and effective method for decontamination of cannabis flower. As such, Regulation 12.065 as currently written is counterproductive.

F. Conclusion

For the reasons set forth herein and in concert with the FDA's position relative to irradiation, RAD respectfully requests that the CCB repeal Reg. 12.065, as confirmation of the fact that the post-harvest treatment of cannabis with irradiation is not dangerous to the health of the consuming public.

Very truly yours,

/s/Kimberly Maxson-Rushton

Kimberly Maxson-Rushton, Esq.

cc: T. Klimas, Executive Director
W. Hartman, RAD
G. Terry, RAD
J. Schwarz, Esq.
E. Hone, Esq.
M. Briggs, SDAG

regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, effective September 15, 2019, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE MA E5 Pittsfield, MA [Amended]

Pittsfield Municipal Airport, MA
(Lat. 42°25′39″ N, long. 73°17′27″ W)

That airspace extending upward from 700 feet above the surface within a 9.6-mile radius of the Pittsfield Municipal Airport, and within 6-miles each side of the 064° bearing of the airport, extending from the 9.6-mile radius to 18-miles northeast of the airport.

Issued in College Park, Georgia, on December 4, 2019.

Ryan Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2019–26857 Filed 12–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA–2017–N–6924]

RIN 0910–AH47

Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule repealing a regulation that requires an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for any drug product that is sterilized by irradiation (the irradiation regulation). Repealing the irradiation regulation will mean that over-the-counter (OTC) drug products that are generally recognized as safe and effective, are not misbranded, and comply with all applicable regulatory requirements can be marketed legally without an NDA or ANDA, even if they are sterilized by irradiation. FDA is taking this action because the irradiation regulation is out of date and unnecessary.

DATES: This rule is effective January 15, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sudha Shukla, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5234, Silver Spring, MD 20993–0002, 301–796–3345.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

In this final rule, FDA repeals the irradiation regulation, which provided that any drug sterilized by irradiation was a new drug. OTC drugs marketed pursuant to the OTC Drug Review that are generally recognized as safe and effective, are not misbranded, and comply with all applicable regulatory requirements now can be marketed legally without an FDA-approved NDA or ANDA, even if the drugs are sterilized by irradiation. As the Agency explained in the proposed rule published in the **Federal Register** of September 12, 2018 (83 FR 46121), FDA is taking this action because the Agency no longer concludes that drugs sterilized by irradiation are necessarily new drugs. The technology of controlled nuclear radiation for sterilization of drugs is now well understood. In addition, drugs that are marketed pursuant to the OTC Drug Review must be manufactured in compliance with current good manufacturing practices (CGMPs). Appropriate and effective sterilization of drugs, including by irradiation, is adequately addressed by the CGMP requirements. Repealing the irradiation regulation eliminates a requirement that is no longer necessary and will not diminish public health protections.

The estimated one-time costs of this rule range from $25 to $32. Avoiding the unnecessary preparation and review of a premarket drug application will generate an estimated one-time cost savings that range from about $0.40 million to $2.16 million. Over 10 years with a 7 percent discount rate, the annualized net cost savings range from $0.05 million to $0.29 million, with a primary estimate of $0.06 million; with a 3 percent discount rate, the annualized net cost savings range from $0.05 million to $0.25 million, with a primary estimate of $0.05 million. Over an infinite horizon, we assume that one sponsor will benefit from this deregulatory action every 10 years; the present value of the net cost savings over the infinite horizon range from $0.76 million to $4.11 million with a 7

percent discount rate and from $1.52 million to $8.21 million with a 3 percent discount rate.

II. Background

On February 24, 2017, E.O. 13777, "Enforcing the Regulatory Reform Agenda" (*https://www.gpo.gov/fdsys/pkg/FR-2017-03-01/pdf/2017-04107.pdf*) was issued (82 FR 12285). One of the provisions in the E.O. requires Agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As part of this initiative, FDA is repealing the irradiation regulation as specified in this rule.

In the November 29, 1955, issue of the **Federal Register**, FDA issued a statement of interpretation relating to the sterilization of drugs by irradiation (20 FR 8747 at 8748).[1] In the statement, FDA explained that there was an interest in the utilization of newly developed sources of radiation for the sterilization of drugs. The Agency went on to state that it was necessary in the interest of protecting the public health to establish by adequate investigations that the irradiation treatment does not cause the drug to become unsafe or otherwise unsuitable for use. For this reason, all drug products sterilized by irradiation would be regarded as new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(p)), which would mean that an effective new drug application would be required for such products.

In 1996, FDA proposed to revise the statement and consolidate it with similar provisions into a single list of drugs that have been determined by previous rulemaking procedures to be new drugs within the meaning of section 201(p) of the FD&C Act (61 FR 29502 at 29503 to 29504 (June 11, 1996)). The Agency proposed to remove from the regulatory text any existing background information describing the Agency's basis for its determination of new drug status.

In 1997, FDA finalized these provisions, now located in § 310.502 (21 CFR 310.502), entitled "Certain drugs accorded new drug status through rulemaking procedures" (62 FR 12083 at 12084 (March 14, 1997)). Section 310.502(a) sets forth a list of drugs that have been determined by rulemaking procedures to be "new drugs" within the meaning of section 201(p) of the FD&C Act. Included on the list was "[s]terilization of drugs by irradiation" (§ 310.502(a)(11)). Because this regulation reflected an FDA determination that the drugs on the list are "new drugs," an NDA or ANDA had to be submitted and approved by FDA before those drugs could be marketed legally.

When the paragraph now reflected in § 310.502(a)(11) was published in 1955, the technology of controlled nuclear radiation for sterilization of drugs was not well understood. In addition, neither the OTC drug monograph system nor the CGMP requirements existed. The authorizing legislation that the CGMP regulations implement, section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), was enacted in 1962 ("Drug Amendments of 1962," October 10, 1962, Public Law 87–781, Title I, sec. 101), and the first CGMP regulations followed in 1963 ("Part 133—Drugs; Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding," 28 FR 6385 (June 20, 1963) available at: *https://www.loc.gov/item/fr028120/*). The regulations creating procedures for establishing OTC drug monographs were issued in 1972 (37 FR 9464 (May 11, 1972)) available at: *https://www.loc.gov/item/fr037092/*).

Today, as the proposed rule explained (83 FR 46121 at 46123 to 46124), the technology of controlled nuclear radiation for sterilization of drugs is well understood, and all drug products marketed under the OTC Drug Review are subject to the requirement set forth in 21 CFR 330.1(a) that they be manufactured in compliance with current good manufacturing practices, as established by parts 210 and 211 (21 CFR parts 210 and 211). The CGMP requirements in parts 210 and 211 encompass sterilization, including by irradiation. As a result, as discussed in the proposed rule (83 FR 46121 at 46124), § 310.502(a)(11) can be repealed and manufacturers will still be obligated to ensure that, if they use radiation: (1) The drug products that they purport to be sterile are in fact sterile and (2) their use of radiation does not have a detrimental effect on their drug products' identity, strength, quality, purity, or stability.

III. Legal Authority

We are issuing this final rule under the drugs and general administrative provisions of the FD&C Act (sections 201, 301, 501, 502, 503, 505, 510, 701, 702, and 704 (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371, 372, and 374)) and under section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). The FD&C Act gives us the authority to issue and enforce regulations designed to help ensure that drug products are safe, effective, and manufactured according to current good manufacturing practices, while section 361 of the PHS Act gives us the authority to issue and enforce regulations designed to prevent the introduction, transmission, or spread of communicable diseases.

IV. Comments on the Proposed Rule

We received five comment letters on the proposed rule by the close of the comment period, all from individuals. Each of the five comment letters contained general remarks supporting the proposed rule.

V. Effective Date

This final rule is effective January 15, 2020.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under E.O. 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). E.O. 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this final rule is not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because few entities will be affected and the net effect will be cost savings to affected firms, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by

[1] Available at: *https://www.loc.gov/item/fr020231/*. A month later, this provision was included in § 3.45 in the republication of chapter 21 of the Code of Federal Regulations (CFR) in the **Federal Register**. See 20 FR 9525 at 9554 (December 20, 1955), available at: *http://cdn.loc.gov/service/ll/fedreg/fr020/fr020246/fr020246.pdf*. In 1975, FDA republished and recodified the rule in 21 CFR 200.30. See 40 FR 13996 at 13997 (March 27, 1975), available at: *https://www.loc.gov/item/fr040060/*.

State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

Table 1 summarizes our estimate of the annualized costs and benefits of the final rule.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE RULE

[$ million]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$0.06	$0.05	$0.29	2018	7	10	Benefits are cost savings.
	0.05	0.05	0.25	2018	3	10	Benefits are cost savings.
Annualized Quantified				2018	7	10	
				2018	3	10	
Qualitative							
Costs:							
Annualized Monetized $millions/year	0.00	0.00	0.00	2018	7	10	Less than $100.
	0.00	0.00	0.00	2018	3	10	Less than $100.
Annualized Quantified				2018	7	10	
				2018	3	10	
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year	0.16	0.16	0.16	2018	7	10	User Fee.
	0.14	0.14	0.14	2018	3	10	User Fee.
	From:			To:			
Other Annualized Monetized $millions/year				2018	7	10	
				2018	3	10	
	From:			To:			

Effects:
State, Local, or Tribal Government: None.
Small Business: None.
Wages: None.
Growth: None.

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. With a 7 percent discount rate, the estimated annualized net cost-savings equal $0.06 million in 2016 dollars over an infinite horizon. Based on these cost savings, this final rule would be considered a deregulatory action under E.O. 13771.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY

[In $ millions 2016 dollars, over an infinite horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Present Value of Cost Savings	0.88	0.75	4.01	1.75	1.50	8.01
Present Value of Net Costs	(0.88)	(0.75)	(4.01)	(1.75)	(1.50)	(8.01)
Annualized Costs	0.00	0.00	0.00	0.00	0.00	0.00
Annualized Cost Savings	0.06	0.05	0.28	0.05	0.05	0.24
Annualized Net Costs	(0.06)	(0.05)	(0.28)	(0.05)	(0.05)	(0.24)

Note: Net costs are calculated as costs minus cost savings. Values in parentheses denote net negative costs (*i.e.*, cost-savings).

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget

under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in E.O. 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in E.O. 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the E.O. and, consequently, a tribal summary impact statement is not required.

XI. Reference

The following reference is on display in the Dockets Management Staff (see ADDRESSES), and is available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at *https://www.regulations.gov*. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Final Regulatory Impact Analysis, "Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation," available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm*.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 360hh–360ss, 361(a), 371, 374, 375, 379e, 379k–1; 42 U.S.C. 216, 241, 242(a), 262.

■ 2. In § 310.502, revise paragraph (a) introductory text and remove and reserve paragraph (a)(11) to read as follows:

§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph (a) have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. An approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act and part 314 of this chapter is required for marketing the following drugs:

* * * * *

Dated: December 9, 2019.

Brett P. Giroir,

Acting Commissioner of Food and Drugs.

[FR Doc. 2019–27046 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 812, and 814

[Docket No. FDA–2018–N–0628]

RIN 0910–AH48

Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Required in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule amending requirements for medical device premarket submissions to remove paper and multiple copies and replace them with requirements for a single submission in electronic format. This action would reduce the number of copies in electronic format required, thus improving and making more efficient the FDA's premarket submission program for medical devices.

DATES: This rule is effective January 15, 2020.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Diane Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993, 301–796–6559, email: *Diane.Garcia@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final rule to amend regulations on medical device premarket submissions to remove requirements for paper and multiple copies and replace them with requirements for a single submission in electronic format to improve the FDA's medical device premarket submission program and create a more efficient submission program. Because a medical device premarket submission in electronic format is easily reproducible, the requirement for multiple copies, whether in electronic format or paper form, is no longer necessary. FDA believes it is beneficial to the public to limit any burden and expense to

EXHIBIT "2"

EXHIBIT "2"

Proposed Changes to NCCR Regulation 12.065

New

~~Deleted~~

Added following March 22, 2022 workshop

~~*Removed following March 22, 2022 workshop*~~

Added following May 24, 2022 Board Meeting

~~*Removed following May 24, 2022 Board Meeting*~~

12.065 Cannabis ***treatment*** ~~***and remediation and irradiation***~~ ~~**treated with radiation**~~**.**

12.065 Cannabis ***treatment*** ~~***and remediation and irradiation***~~ ~~**treated with radiation**~~**.** If any cannabis or cannabis product has been treated with ***any thermal*** ~~***heating***~~ ***process,*** ~~***chemical,***~~ ***ionizing radiation,*** ***chemical, or other processes approved by the Board or Board Agent for the purpose of reducing or eradicating*** ~~***preventing***~~ ***microbial*** ~~***decontamination***~~ ***at any time post-harvest, the label must include the method of treatment and the following statement: "***~~***NOTICE: This product has undergone remediation for purposes of decontamination***~~***" treatment using [method of treatment]*** ~~***to ensure compliance with testing standards***~~***" in bold lettering.*** ~~**radiation at any time, any and all packaging of the irradiated cannabis or cannabis product must include labeling that contains the following statement: "NOTICE: This product contains ingredients that have been treated with irradiation" in bold lettering, along with the Radura symbol as used by the U.S. Food and Drug Administration.**~~

Proposed Final:

12.065 Cannabis treatment. If any cannabis or cannabis product has been treated with any thermal process, ionizing radiation, chemical, or other processes approved by the Board or Board Agent for the purpose of reducing or eradicating microbial contamination at any time post-harvest, the label must include the method of treatment and the following statement: "This product has undergone treatment using [method of treatment]" in bold lettering.

EXHIBIT “3”

EXHIBIT “3”

RAD Source Technologies
CCB NCCR 12.065
July 26, 2022

12.065 Cannabis treatment. If any cannabis or cannabis product has undergone remediation to reduce or eradicate microbial contamination the cultivator must include a description of the method of treatment used in the product packaging.

EXHIBIT “4”

EXHIBIT “4”

SETTLEMENT AGREEMENT

This Settlement Agreement (hereinafter "Agreement") is entered into by and between RAD Source Technologies, Inc. ("RAD Source") and The State of Nevada *ex rel.* Department of Taxation, Marijuana Enforcement Division (the "Department"). The parties to this Agreement may be referred to collectively as the "Parties" or individually as a "Party." This Agreement shall be effective as of the date the Agreement is fully executed by all Parties ("Effective Date").

RECITALS

WHEREAS, RAD Source brought claims against the Department in an action styled *RAD Source Technologies, Inc. v. The State of Nevada ex rel. Department of Taxation, Marijuana Enforcement Division,* Case No. A-19-805074-W in the Eighth Judicial District Court in Clark County, Nevada (the "Action");

WHEREAS, on July 8, 2020, the Court in the Action entered an *Order Granting RAD Source Technologies Inc.'s Petition for Writ of Mandamus* (the "Writ");

WHEREAS, on November 5, 2020, the Parties attended a mediation through the Senior Judge Department of the Eighth Judicial District Court, Justice Michael Cherry (Ret.) serving as the mediator, where they reached an agreement to settle the Action and any claims relating to the events that are the subject of the Action;

WHEREAS, the Parties placed the principal terms of their agreement on the record and agreed to memorialize the settlement terms in this Agreement; and

WHEREAS, upon the advice of competent professional counsel, the Parties deem it to be in their respective best interests to enter into this Agreement and intend this Agreement to be a settlement between them which will fully and finally resolve the Action.

NOW THEREFORE, in consideration of the conditions and mutual covenants set forth herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereto agree to the following:

TERMS

1. RECITALS

1.1 The above Recitals are true and correct and are made a substantive part of this Agreement.

2. SETTLEMENT

2.1 Pursuant to Nevada Revised Statutes ("NRS") § 678A.460 and Nevada Cannabis Compliance Board Regulation ("NCCR") 4.145, RAD Source shall file a petition (the "Petition") with the Cannabis Compliance Board (the "CCB") for the amendment or repeal of NCCR 12.065 (the "Labeling Regulation").

2.1.1 Within three (3) judicial days of the Effective Date or as soon as reasonably possible after the Effective Date, the Department shall deliver to RAD Source's counsel a payment of $500.00 to reimburse RAD Source for the filing fee for the Petition.

2.2 Pursuant to NCCR 4.145(6), upon receipt of the Petition the CCB will provide public notice of said filing at the next CCB Meeting held fifteen (15) days thereafter. In addition, the CCB has scheduled a public workshop on January 19, 2021 with respect to the Labeling Regulation to be chaired by CCB Board Member Dr. Bryan Young. The CCB shall provide notice of the public workshop to the Nevada cannabis industry.

2.3 Within twenty one (21) calendar days of the Effective Date, the CCB shall provide notice to the Nevada cannabis industry that NCCR 12.065 as presently adopted is applicable to all forms of radiation used, at any time, to treat cannabis.

3. DISMISSAL OF THE ACTION

3.1 Within three (3) judicial days of the Effective Date of this Agreement, RAD Source shall file with the Court in the Action a stipulation and order for dismissal with prejudice in the form attached hereto as "**Exhibit 1**".

3.2 Notwithstanding the dismissal of the Action as provided in this Agreement, the findings of fact, conclusions of law, and order of the Court in the Action as set forth in the Writ shall remain in full force and effect and shall remain binding on the Parties and their successors-in-interest.

3.3 The dismissal of the Action as provided in this Agreement shall pertain only to the allegations, claims, and defenses asserted by the Parties in their respective pleadings in the Action, and shall not be construed as a waiver or release of any allegations, claims, or defenses not pled in the Action.

3.3.1 Specifically, RAD Source expressly reserves any and all claims, rights, and remedies, at law and in equity, against the CCB with respect to, *inter alia*, compliance with the Writ and the Labeling Regulation. The CCB expressly reserves any and all defenses, at law and in equity, brought by RAD Source.

4. REPRESENTATIONS AND WARRANTIES

4.1 In the event that the Department is no longer responsible for performing any of the conditions, obligations, and/or requirements in this Agreement, then the entity that is responsible for performance of same (i.e., the CCB or any related entity or successor-in-interest thereto) shall

be subject to the conditions obligations, and/or requirements in this Agreement. The Department represents and warrants that the Chair of the CCB approved the terms of Section 2 of this Agreement, agrees to the conditions obligations, and/or requirements in this Agreement, and will request approval by the CCB at its next meeting, and the Department has authority to enter into and sign this Agreement.

5. NO ADMISSION

5.1 The Parties, and each of them, hereby acknowledge and agree that this Agreement is entered into as a mutual compromise and settlement that is not in any respect or for any purpose to be deemed or construed as an admission or concession of any improper or unlawful conduct and/or any liability whatsoever.

6. ADVICE OF COUNSEL

6.1 Each party represents and warrants that it has consulted with and received the advice of independent legal counsel prior to signing this Agreement or otherwise elected to waive its rights to seek the advice of counsel with respect to this Agreement and any negotiations in connection therewith, and acknowledges that no other party or agent or attorney of any other party has made any promise, representation, or warranty whatsoever, express or implied, not contained herein, concerning the subject matter hereof or to induce the party to sign this Agreement.

7. ENTIRE AGREEMENT

7.1 It is expressly understood and agreed that this Agreement contains the entire agreement and understanding of the Parties concerning the subject matter hereof, and that this Agreement supersedes all prior negotiations and agreements between the Parties hereto, whether written or oral. It is further expressly understood and agreed that there have been no promises, agreements, warranties or inducements not herein expressed, made to either party. The Parties hereto acknowledge that they have read this Agreement and are executing it without relying upon any statements, representations or warranties, written or oral, which are not expressly set forth herein.

8. WAIVER, MODIFICATION AND AMENDMENT

8.1 No provision of this Agreement may be waived unless in writing and signed by the party or parties whose rights are thereby waived. Waiver of any one provision herein shall not be deemed a waiver of any other provision herein. This Agreement may be modified or amended only by written agreement executed by the Parties hereto.

9. NOTICES

9.1 All notices or demands of any kind that any party is required or desires to give or make upon others in connection with this Agreement shall be in writing and shall be deemed to be delivered by depositing the notice or demand in the United States mail, postage prepaid, and addressed to the other party and sending a copy of the notice or demand via e-mail as follows:

If to RAD Source:

Joel Schwarz
H1 Law Group
701 North Green Valley Parkway, Suite 200
Henderson, NV 89074
joel@h1lawgroup.com

If to Department:

Michelle Briggs
Senior Deputy Attorney General
Office of the Attorney General
555 E. Washington Avenue, Suite 3900
Las Vegas, NV 89101
mbriggs@ag.nv.gov

10. INTERPRETATION

10.1 This Agreement was drafted through the joint efforts of the Parties and/or through counsel, and shall not be read for or against any party to this Agreement on that account.

10.2 If any term, paragraph, condition or covenant of this Agreement or the application thereof to any party or circumstance shall, to the extent, be held invalid or unenforceable, the remainder of this Agreement, or the application of such term, provision, condition or covenant to persons or circumstances other than those as to whom or which it is held invalid or unenforceable, shall not be affected thereby, and each term and paragraph of this Agreement shall be valid and enforceable to the fullest extent permitted by law, and said invalid or unenforceable term, provision, condition or covenant shall be substituted by a term, paragraph, condition or covenant as near in substance as may be valid and enforceable.

10.3 This Agreement is intended to be enforced according to its written terms under the laws of the State of Nevada.

11. BENEFIT

11.1 This Agreement shall be binding upon and inure to the benefit of the Parties, and each of them, their heirs, spouses, dependents, beneficiaries, assigns, attorneys, agents, partners, trustees, successors, assigns, affiliates, personal representatives, and any and all other persons acting on the party's behalf. Except as expressly provided herein, nothing in this Agreement is intended to confer on any other person or entity any rights or remedies under or by reason of this Agreement.

12. ATTORNEYS' FEES

12.1 If any action is brought to enforce this Agreement, or is brought in connection with any Future Dispute arising out of this Agreement or the claims which are the subject of this Agreement, the prevailing Party or Parties shall be entitled to recover damages, fees and other costs incurred in such litigation which they may prove are the direct and proximate result of any breach hereof in addition to any other relief which that Party or Parties may be entitled to by law.

13. COUNTERPARTS

13.1 This Agreement may be executed in any number of counterparts and each counterpart executed by any of the undersigned together with all other counterparts so executed shall constitute a single instrument and agreement of the Parties. Facsimile or emailed PDF copies hereof and signatures hereon shall have the same force and effect as originals.

14. AUTHORITY TO SIGN

14.1 Each party warrants that it has the authority to sign this Agreement, and each individual executing this Agreement on behalf of any entity specifically warrants that he/she has the authority to bind that entity by his/her signature.

IN WITNESS WHEREOF, THE PARTIES HERETO HAVE EXECUTED THIS AGREEMENT AND THE PARTIES AFFIRM AND WARRANT THAT THEY HAVE REVIEWED THE ABOVE AND SPECIFICALLY AGREE TO THE CONTENTS.

RAD SOURCE TECHNOLOGIES, INC.

By: William Hartman
Its: CEO

Dated: December ____, 2020.

THE STATE OF NEVADA *ex rel.*
DEPARTMENT OF TAXATION

Melanie Young
By: Melanie Young
Its: Executive Director

Dated: December 18, 2020.

Comments on NCCR 12.065 - Cannabis treatment

July 26, 2022 public hearing

Submitted by:
Jill Ellsworth, Founder & CEO
On behalf of Willow Industries, Inc.

Thank you for the opportunity to comment on the latest draft of NCCR 12.065, the regulation concerning labeling requirements for cannabis that has been treated.

From the start of this rulemaking process in 2020, we have been supportive of the Board's efforts to improve transparency around cannabis decontamination and remediation, and believed that providing information on product labels was an appropriate and effective way to educate patients and adult consumers.

People who consume cannabis and cannabis products in Nevada deserve to know how those products were produced so that they can make informed decisions, and mandatory labeling of treatment processes is an important tool to achieve that goal. This is also a positive step towards applying standards that are already commonplace in other industries. For example, in the food industry all pasteurized milk includes "Pasteurized" on its label, which helps individual consumers understand the product they are buying while educating the public about the measures put in place to keep their food safe.

Of course, the details of what goes onto the label are tremendously important — a poorly worded label could confuse rather than inform, or cause fear instead of reassurance. This is not a reason to abandon such labels altogether, but instead to be careful about the wording. Since the first public workshop on January 19, 2021, this rule has undergone multiple revisions, slowly improving after significant input from stakeholders. We greatly appreciate the work that the Board has put into this rule throughout its many iterations, and think that the language is nearly ready for adoption.

We do have one remaining suggestion on the content of 12.065 that we think would improve this regulation for both consumers and the industry: replacing the language "to ensure compliance with testing standards," which was removed from the label in the latest draft, with alternative language that informs readers of the purpose of such treatment.

Recommendation: Replace "to ensure compliance with testing standards" with alternative language explaining reasoning for the treatment

This latest draft removed "to ensure compliance with testing standards" from the mandatory labels for treated cannabis or cannabis products, with the label now only saying "This product has undergone treatment using [method of treatment]." We believe that the removal of this language makes the label less useful to consumers and could cause confusion around products bearing such a label.

While some consumers are familiar with cannabis treatment, most are not, and the deleted language provided important context for the purpose of treatment: to ensure compliance with testing standards. Without it, uninformed consumers may incorrectly assume that such treatment was done for other reasons and be discouraged from purchasing a safe product.

It is important that the mandatory label not only explains what method of treatment was used, but also the reasoning for such treatment: to protect public health and safety by reducing the number of microbial contaminants to levels compliant with the Board's standards.

We would be comfortable with restoring the deleted language, but if the Board would prefer new language, we suggest the following replacement:

> "To protect public health and safety, this product has undergone treatment using [method of treatment]."

This simple and concise message would help educate consumers while avoiding any unfounded fears around approved treatment methods.

Conclusion

Thank you again for your consideration. Please do not hesitate to contact us if you have any questions or would like additional information.

Submitted by,

Jill Ellsworth
Founder / CEO
Willow Industries, Inc.
jill@willowindustries.com
www.willowindustries.com

Cannabis Compliance Board
Executive Assistant
regulations@ccb.nv.gov

Re: Hearing on 7/26/2022 – Statement regarding Regulations

Dear CCB:

We want to thank you for your time and allowing us the opporutinty to submit our statement. We are submitting this letter to request one more public workshop regarding the Nevada Compliance Regulation 12.065, as we feel there are still numerous questions unanswered.

To start off, we must review the stance of the FDA. In 2019, the FDA repealed the requirements for the Radura symbol and warnings for all OTC medications, wherein Cannabis would fall. The FDA use of the warning is being used as a basis for the CCB's adoption of the sympbol, however the FDA is now finding it is no longer necessary. As the FDA has made it clear where they stand, we should properly follow their lead and guidance.

Further, the new regulations mention the need for labeling "post harvest", but does not clarify what "post harvest" entails? What are the limitations? What is the timing? What is included? It does not make it clear, and therefore does not outline what products would be required to be labeled.

Finally, there has been no education for the consumer regarding the process and the safety. There needs to be education and training not only of the consumer directly, but also the retailers who are the final contact with the consumer and would help with education.

As there are so many questions outstanding, we feel there needs to be another workshop to discuss the numerous concerns. Not only do the consumers need to be provided more information, but also the cultivators and producers need more guidance regarding application of the regulation, the labeling requirements and the process to be used.

Once again, we thank you for the opportunity in participating in this process.

Sincerely,

Pateel Arakelyan, Esq.
Director of Compliance and Associate General Counsel

3950 North Bruce St
North Las Vegas, NV 89030
(702) 623-2919