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NSF Leaders On How New Cosmetics Certification Could Bolster MoCRA Compliance

by Ryan Nelson

NSF's Contents and Claims Certified Guideline for beauty and personal-care products should position companies well for compliance with new US regulations under the Modernization of Cosmetic Regulations Act, the organization says. NSF senior leaders discuss in an interview with HBW Insight.

Certification to NSF's new Guideline 527, Contents and Claims Certified for cosmetic and personal-care products could be a good start to compliance with new US regulations under federal cosmetics reform legislation enacted at the end of 2022, the independent, not-for-profit public health organization says.

Announced on 6 March, Guideline 527 "provide[s] a complete program that includes standardized definitions and criteria, label review, formulation requirements, ingredient identity, testing criteria, product purity and physical characterization, and Good Manufacturing Practice (GMP) compliance," according to Ann Arbor, MI-based NSF.

"Building on its decades of experience in the certification of dietary supplements, NSF developed Guideline 527 to offer its expertise in mitigating risk, minimizing liability, differentiating products from competitors, and improving trust among customers to the personal care industry," NSF says.

Further, the guideline "aligns" with MoCRA.

The US Modernization of Cosmetic Regulations Act (MoCRA), signed into law in December by President Joe Biden, requires companies to register facilities and list products and ingredients with the US Food and Drug Administration by the end of 2023. Industry stakeholders are waiting

on FDA instruction on how to do that, whether through the same portal used for the Voluntary Cosmetic Registration Program or another channel. (Also see "*MoCRA: No User Fees, Not Overly Prescriptive, And Could Help Tamp Down State Legislation*" - HBW Insight, 5 Mar, 2023.)

They also await guidance on serious adverse event reporting mandated by MoCRA, as well as FDA rulemaking to establish good manufacturing practices for the cosmetics industry, which the law requires to be finalized within three years.

KATHERINE FILLINGER, SENIOR MANAGER, GLOBAL CERTIFICATION

Despite numerous unknowns, industry is being advised to get moving, and NSF believes Guideline 527 could take companies a good distance toward compliance, however future guidances and implementing regulations take shape.

For example, "Industry is really wondering what the FDA is going to do with the GMPs. I don't think anybody's expecting that the FDA is going to be coming up with something entirely new right? They haven't done that for dietary supplements. There's a general global consensus around quality management systems and best practices," said NSF's Brandi Reinbold, senior manager, technical, global certification, in an 8 March interview with HBW Insight. (Also see "*MoCRA Confidentiality For AE Reports? And Other Questions Raised At IBA Regulatory Forum*" - HBW Insight, 7 Mar, 2023.)

She said NSF/ANSI 455-3 Good Manufacturing Practices standard for cosmetics is "wholly inclusive" of ISO 22716 for cosmetic GMP certification, as well as the FDA's draft guidance on cosmetic GMPs.

"Becoming GMP-compliant when you have none is probably the most difficult compliance aspect of MoCRA. … Becoming GMP-certified would be a huge step in the right direction," Reinbold said.

She noted that NSF's GMP certification includes requirements for adverse event reporting, "so GMP-certified companies will have procedures in place in advance of the MoCRA implementation date."

Katherine Fillinger, senior manager, global certification, described Guideline 527 as "our passion project for the past couple of years" and a

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revamp of the NSF Product Verified program introduced in April 2017, which was put on ice by the end of that year. (Also see "*NSF International Launches Cosmetic Verification Program For 'Consumer Assurance'*" - HBW Insight, 18 Apr, 2017.)

"Timing is everything, right? The industry wasn't there yet. I think that they are very much in need now," she said.

Additional comments below from Fillinger and Reinbold have been lightly edited for length and clarity.

Q HBW Insight: Can you talk a bit about how the certification process to Guideline 527 is going to work? How long should companies expect the process to take, generally speaking, and what can you say about cost?

A Brandi Reinbold: There are a couple of different elements of it. First, the audit is required. That process from application typically takes about 90 days. That's a good outcome – it depends on how that the facility performs. And it's a little over $11,000 for our domestic clients, but that can vary based on facility size, technologies, and products they manufacture. NSF can provide a free quote to any client looking to gain specific costs for their facility. So that's the GMP start. And you have to have that completed before you can apply for a product certification because we want to make sure that the facility has been evaluated and is in in good standing with NSF/ANSI 455-3 [Cosmetics] or NSF/ANSI 455-4 [OTC drugs] as applicable. Then the second piece is the certification process. That's going to start with obtaining all of the necessary documentation. So your product labels and marketing documents, formulations – NSF really starts from that evaluation point. We determine the testing based on the product itself, so if it has botanicals, for example, we're going to do the ID testing of the raw materials. The testing we'd expect to complete in about 30 days, moving then to certification if everything passes. So ideally, that process is, again,

about a 90-day cycle with nothing going wrong.

Q **Your release notes testing for microbiology, heavy metals, adulterants, product stability, efficacy, preservation, and safety, as well as any potential interactions with other products or substances.**

A Katherine Fillinger: There's a lot of back and forth, a lot of documentation. We want to leverage our experience in where the risk lies to determine if it makes sense for us to do that extra deep dive, or for us to do the testing. There are a lot of product recalls around contamination, and that's why contamination is something that we will be doing testing on – we won't be taking manufacturer data – because there is risk there. But we don't want to wear out the industry with a ton of efforts being duplicated. We want to leverage their product knowledge – they know the product better than anybody – but we just want them to show us what they've done. And we'll evaluate it to the criteria to make sure that it meets that unified standard starting line for them to go forward.

Q **On recalls, you note in your announcement that there have been 117 cosmetic product recalls since 2018, and we've seen that contamination is the leading factor.**

A Reinbold: We've looked into them very deeply. Seventy percent of them were microbial contamination, and the rest were mostly ingredient-based adulterants or manufacturing contaminants. You can’t stress enough how important GMP controls are to mitigating those risks.

Q **What happens if a company fails the initial GMP audit?**

A Fillinger: It’s a violation of our accreditation to provide consulting. NSF does have a consulting business, and we will refer companies to consulting if we feel that they need consulting to pass an audit. But it's not a part of the certification offering, and they don’t have to use [NSF Consulting]. We don't want to know what happens on the consulting side. We want it to be a truly independent review.

Q **MoCRA requires the FDA to issue regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. It also directs the agency to assess and report findings related to use of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products.**

A Reinbold: Both of these are part of our certification program. Every product is required to be tested for PFAS. Products with talc will have their raw material tested. So if compliance is a concern, certified companies will have data backing up their products and a reasonable expectation that they wouldn't have any difficulty in an FDA audit.

Q **Does NSF do all the testing itself?**

A Reinbold: NSF either does the testing or subcontracts it. We're an ISO-accredited certification body. That means that our lab is ISO 17025-accredited, and any subcontractor that we use also needs to be ISO 17025-compliant, because we are trying to incorporate a lot of adulterant testing that is kind of emerging. Where a method might not have an international standard, we follow international standards of methods validation to acquire new methods.

Q **Industry stakeholders are eager for FDA guidance on MoCRA provisions defining a 'safe' cosmetic and adequate safety substantiation. To what extent would NSF certification support a company's safety substantiation work?**

A Reinbold: Because we don't know what the FDA is going to come up with regarding expectations for the safety assessments, it's really hard to say right now whether the program would make their substantiation easier or not. Certainly having a lot of data on the purity of your product wouldn't hurt. But there is no consumer use component to this, so it may be that we don't know yet.

Q **NSF certification also includes a label review to ensure claims made on product are accurate and truthful. Can you give examples of claims you expect to evaluate?**

A Reinbold: We are limiting our claims review for the time being to basically what I would consider purity-related claims, things like 'free of' claims. We've addressed some additional requirements around formulation when making claims like 'clean' and 'hypoallergenic,' but with respect to setting a full standard, that remains a test for the future. For the time being, any type of 'free of' claim – you know, free of parabens, even claims like 'vegan,' free of animal-based products, or 'natural,' free of synthetic ingredients. We would do a formulation review; there would be no analytical testing for a natural claim. For organic claims, we're requiring organic certification by a third party, and we will verify that that certification is current. And we will monitor that on a yearly basis. The same for cruelty-free claims.

Q **All claims that we've seen targeted by class action plaintiffs through the years.**

A Fillinger: We want to reduce risk; we can't promise that we'll eliminate risk. When someone else is checking your work, gaps can be identified much more effectively and efficiently. I always compare it to when you turn in your paper to your teacher, and you think it's flawless. And then you get it back with a grade and edits and you're like, 'Whoa! How did I miss that?' That's the third-party lens that we are able to provide.

Q **How else has NSF certification benefited companies, for example in the dietary supplement space?**

A Fillinger: Some of our companies have had greater access to retailers because of certification. And that is because the retailers are looking to reduce the risk to their consumers, as they've been pulled into the accountability for distribution of products. And third-party certification can actually reduce the cost of your insurance premiums. We are an independent public health agency. We don't sell anything, we don't have widgets, all we are is our name and our reputation. And we take that extremely seriously, and that is why that credibility of having a third party like NSF stand behind your brand means something.