OTC Monograph Reform – Frequently Asked Questions

CHPA Activities

Q.1. – Will CHPA be creating a standing group to anticipate submissions based on FDA’s dashboard? – Yes, as member interest become clear, CHPA will establish a variety of working groups to share information and develop input for FDA.

Q.2. – Will CHPA proactively propose priorities for FDA’s dashboard?  CHPA will be asking members if this is of interest and if so, will assemble a group to develop the input.

FDA Activities

Q.1. – Where will AOs be published? – AOs will be published on a new webpage on FDA’s website. The notification of an AO or proposed AO will be published in the Federal Register. CHPA members will receive notification of published AOs via the daily Federal Register distribution.

Q.2. – As monographs are finalized, will they be removed from the CFR? – Monographs are now administrative orders rather than “regulations,” so at some point as FDA builds a website to house them and catalogs them, FDA can remove monographs from the CFR and announce the action in the Federal Register. Meanwhile, regulations of general applicability (Drug Facts, definitions of general recognition, etc.) currently in the CFR would remain there.

Q.3. – Will FDA be updating their list of Cat 1, 2 and 3 ingredients, dated April 2010? – We will encourage FDA to do this but know of no plans to do so. Currently, to determine the regulatory status of an ingredient, one may need to review FDA’s list from 2010 and review the relevant rulemaking history (CFR or FDA website).

Q.4. – Is there any documentation or understanding with FDA that they will not investigate final monographs or Cat 1 ingredients? – No, in fact, just as today, under the situation of new data or information that results in a concern about an ingredient, regardless of GRASE status, FDA could investigate the need for updated labeling or additional data to reassure GRASE status.

Q.5. – Is there a process to request an extension for removal of Cat 2 ingredients from the market within 6 mos. of passage of legislation? – Any company marketing a Cat 2 ingredient should contact FDA with their plans to remove the ingredient or plan to generate additional data, which could include a request for an extension of the timeline.

Q.6. – Will FDA update the Goals Letter to reflect accurate dates? – We expect FDA to do this.

April 23, 2020
CHPA
Fees

Q.1. – Are facilities producing only homeopathic products subject to a fee? – No

Q.2. - What is the basis for fees? – Fees are based on a fee per OTC monograph facility necessary to generate the applicable fiscal year’s target user fee revenue (including any inflation or operating reserve adjustments). OTC monograph facilities are those that manufacture or process an OTC monograph drug in finished dosage form. Research and testing labs exempt. Separate buildings in one location under same local management = single facility. The contract manufacturing organization facility fee is 2/3 full fee (contract manufacturers are those who manufacture or process OTC monograph drugs in finished dosage form but do not sell directly to wholesalers, retailers, or consumers). In a formula, Fee = (Total annual fee target +/- adjustments) ÷ (OTC monograph facilities + [CMO monograph facilities x 2/3])

Q.3. – When are fees due? In 2020, the later of July 1, 2020, or 45 days after FDA publishes the fee. In future years, fees are due the later of the first business day of June or the first business day after enactment of appropriations authority.

Q.4. – Are there any options for a fee waiver? – No.

Q.5. – Where and when should we update facility registrations? Through FDA’s Drug Registration and Listing System. Fees for a given fiscal year will be based off of OTC monograph facilities in the system as of December 31 of the previous fiscal year.

Q.6. – Will there be adequate progress made by Year 3 to consider whether there should be an OMUFA II to ensure the benefit warrants the new costs to industry? - Speculative, but that remains to be seen. It’s in FDA’s interest for this program to be a success, but many goals are not measured until year 4, which should provide a clearer picture of progress.

Q.7. – Is the facility fee a set amount? – Yes, the fee is set each year. Manufacturers pay the fee published each year and contract manufacturers pay 2/3 fee.

Q.8. – If OTC Monograph and OTC NDA products are made in the same facility, do you pay both fees? – Yes, similar to the current situation where OTC NDA and Rx products may be made in the same facility.

Q.9. – What are the key dates regarding facility registration and paying fees? For 2020: FDA will publish fees as soon as mid-May; fees will be due the later of 45 days after publication or July 1. For 2021-2024: December 31 = facility snapshot date. Mid-March = fees published. 1st business day of June = fees due.

Q.10. – Will companies manufacturing hand sanitizers under Emergency Use Authorization due to COVID-19 be subject to user fees? If the product makes a drug...
claim (ie, if it’s under the antimicrobial handwash or handrub monograph), yes, so long as the company hasn’t stopped manufacturing by December 31, 2020.

Q.11. – Will fees apply to relabelers/repackagers? Relabelers, yes, as they are processing an OTC monograph drug in finished form. Repackagers? It depends. If they aren’t changing the original label (such as a gift pack or a multi-product kit), no.

Q.12. – Do fees apply to foreign facilities? Yes.

Innovation

Q.1. – Can OMORs be submitted for a Cat 3 ingredient? Ingredients must be GRASE (Cat 1) before they can be the subject of an innovation OMOR. Data to support GRASE status for a Cat 3 ingredient may be submitted either before an OMOR for innovation or in parallel with an OMOR for innovation.

Q.2. – Can anyone submit a request to move an ingredient under an OTC NDA to GRASE status or must that be done by the RLD holder? – Anyone can submit such a request via an OMOR.

Q.3. – Can the order process be used to switch a drug from Rx to OTC status? – Maybe but unlikely – Most first in class switches are submitted via NDA or SNDA, providing FDA significantly more oversight and interaction with the sponsor than for OTC Monograph products. FDA has complete discretion to reject an OMOR filing if the ingredient does not have information to show safe use under comparable conditions.

Q.4. – What will FDA consider confidential information or trade secret and not publish? – When FDA publishes a proposed order for public comments, they intend to publish the information necessary to support a determination of GRASE. A sponsor may mark certain information “confidential” and discuss with FDA what will be disclosed.

Q.5. – Would a novel dosage form qualify as a Tier 2 submission? – No, there is a specific list of Tier 2 submissions in the legislation. Anything not on that list (including new dosage forms) is considered Tier 1.

Q.6. – Will FDA award exclusivity to the first to file an innovation? Exclusivity is based on the first to final order publication.

Q.7. – Could you submit an OMOR for a patented technology that retains patent exclusivity past the time of exclusivity for the OMOR? – Yes, patent-related exclusivity is independent of OMOR exclusivity.

Q.8. – Do we know what content/format is needed for OMOR and GRASE submissions? – FDA will issue guidance, but for now, they have suggested referring to guidance for sunscreens.
Labeling
Q.1. – Since Cat 1 ingredients in a TFM are now “final”, how quickly must product labeling be updated? – While there is no firm deadline in the legislation, it is prudent to update labeling to comply with final monographs.

Nomenclature
AO – Administrative Order
CDER – Center for Drug Evaluation and Research (FDA)
CFR – Code of Federal Regulations
GRASE – Generally Recognized and Safe and Effective
OMOR – OTC Monograph Order Request
OMUFA – OTC Monograph User Fee Act (former name for legislation; now, CARES Act)
RLD – Reference Listed Drug
TFM – Tentative Final Monograph

Q.1. Will the regulatory pathway still be called the OTC Monograph pathway? - Yes

Timing
Q.1. What is the first fiscal year for the legislation? – FY 2021, which starts on October 1, 2020
Q.2. Will FDA allow OMOR submissions right away? – Although not under specific metrics and goals, FDA has stated that as resources permit, they will schedule meetings with sponsors and accept OMORs.