

Rulemaking History for OTC Ophthalmic Drug Products

Final Monograph (21 CFR part 349 (<https://www.gpo.gov/fdsys/pkg/CFR-2006-title21-vol1/content-detail.html>)):

Ophthalmic Drug Products for Over-the-Counter Human Use

OTC Ophthalmic Drug Products found on this page:

- [Original Active Ingredients and Labeling](#)
- [Emergency First Aid Eyewashes](#)
- [Contact Lens Solution](#)
- [Vasoconstrictor Warning](#)

Ophthalmic Drug Products: Original Active Ingredients and Labeling

Advance Notice Of Proposed Rulemaking	Date	FR Citation
Advance Notice of Proposed Rulemaking	5/6/1980	45FR30002 (http://cdn.loc.gov/service/ll/fedreg/fr045/fr045089/fr045089.pdf#page=201).
Correction	7/22/1980	45FR48920 (http://cdn.loc.gov/service/ll/fedreg/fr045/fr045142/fr045142.pdf#page=81).
Proposed Rule	Date	FR Citation
Tentative Final Monograph	6/28/1983	48FR29788 (http://cdn.loc.gov/service/ll/fedreg/fr048/fr048125/fr048125.pdf#page=132).
Correction	7/19/1983	48FR32837 (http://cdn.loc.gov/service/ll/fedreg/fr048/fr048139/fr048139.pdf#page=98).

Reopening of Administrative Record: Yellow mercuric oxide (anti-infective) excluded from final monograph	3/4/1988	53FR6997 (http://cdn.loc.gov/service/ll/fedreg/fr053/fr053043/fr053043.pdf#page=40)
Final Rule	Date	FR Citation
Final Monograph	3/4/1988	53FR7076 (http://cdn.loc.gov/service/ll/fedreg/fr053/fr053043/fr053043.pdf#page=119)
Correction	4/21/1988	53FR13217 (http://cdn.loc.gov/service/ll/fedreg/fr053/fr053077/fr053077.pdf#page=129)
Technical Amendment: Revises "hydroxypropyl methylcellulose" to "hypromellose"	6/3/2003	68FR32981 (https://www.gpo.gov/fdsys/pkg/FR-2003-06-03/pdf/03-13827.pdf)
Technical Amendment: Clarifies Labeling of Active/Inactive Ingredients	2/19/2003	68FR7919 (https://www.gpo.gov/fdsys/pkg/FR-2003-02-19/pdf/03-3926.pdf)

Ophthalmic Drug Products: Emergency First Aid Eyewashes

Advance Notice Of Proposed Rulemaking	Date	FR Citation
Request or Data	12/5/1989	54FR50240 (http://cdn.loc.gov/service/ll/fedreg/fr054/fr054232/fr054232.pdf#page=19)
Proposed Rule	Date	FR Citation

Proposed Rule	2/19/2003	68FR7951 (https://www.gpo.gov/fdsys/pkg/FR-2003-02-19/pdf/03-3927.pdf)
Final Rule	Date	FR Citation

Ophthalmic Drug Products: Contact Lens Solution

Advance Notice Of Proposed Rulemaking	Date	FR Citation
Notice: Reclassifies contact lens solution from OTC drug to device	3/6/1979	44FR12270 (http://cdn.loc.gov/service/ll/fedreg/fr044/fr044045/fr044045.pdf#page=132)

Ophthalmic Drug Products: Vasoconstrictor Warning

Proposed Amendment of Final Monograph	Date	FR Citation
Proposed Amendment of Final Monograph	2/23/1998	63FR8888 (https://www.gpo.gov/fdsys/pkg/FR-1998-02-23/pdf/98-4531.pdf)
Amendment of Final Monograph	Date	FR Citation
Amendment of Final Monograph	6/21/2000	65FR38426 (https://www.gpo.gov/fdsys/pkg/FR-2000-06-21/pdf/00-15631.pdf)

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