FDA Resources for Angiotensin II Receptor Blockers Voluntary Recalls

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Several medicines containing Angiotensin II Receptor Blockers (ARB) have been the subject of voluntary recalls due to the presence of highly toxic nitrosamine impurities (see Table 1).

USP is adding pop-up text to *USP-NF* Online to call the user's attention to FDA resources about the ARB recall, which will be displayed on 30-Aug-2019 when users access the drug substance and drug product monographs listed in Table 1.

Table 1. ARB monographs that will contain the pop-up text.*

Drug substance	Drug product
Valsartan	Valsartan Tablets Valsartan and Hydrochlorothiazide Tablets Amlodipine and Valsartan Tablets
Losartan Potassium	Losartan Potassium Tablets Losartan Potassium and Hydrochlorothiazide Tablets
Irbesartan	Irbesartan Tablets Irbesartan and Hydrochlorothiazide Tablets

*The list of affected monographs is subject to change as new information becomes available.

Additional information about the recalled ARB products, FDA test methods for detection of nitrosamine impurities, acceptable interim limits for the impurities, and FDA press announcements can be found here:
www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements

FDA also issued a General Advice Letter to ARB manufacturers and applicants regarding FDA's concerns, findings, and recommended actions to ensure the absence of the nitrosamine impurities (or below the interim limits) in these products. The letter can be found here: https://www.fda.gov/files/drugs/published/General-Advice-Letter-ARB.pdf

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