

FDA completed and finalized a form that small businesses may use to apply for an exemption to labeling requirements. The form, Form FDA 3570, contains all of the information required to be submitted by 21 CFR 101.9(j)(18)(iv), which is approved under Control No. 0910-0381. This does not change the burden hours as the information collection requirements have already been approved for that regulation. The form has been added as an instrument to IC #6.