附件12

立卷审查要求（征求意见稿）意见反馈表

单位名称/专家名称： 联系人： 联系电话：

**1《医疗器械产品注册项目立卷审查要求（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**2《医疗器械变更注册项目立卷审查要求（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**3《医疗器械免临床目录对比立卷审查表（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**4《医疗器械临床评价立卷审查表（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**5《体外诊断试剂产品注册项目立卷审查要求（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**6《体外诊断试剂变更注册项目立卷审查要求（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**7《体外诊断试剂临床评价立卷审查表（非临床试验）（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**8《体外诊断试剂临床评价立卷审查表（临床试验）（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**9《医疗器械临床试验审批项目立卷审查要求（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**10《 医疗器械延续注册项目立卷审查要求（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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**11《 体外诊断试剂延续注册项目立卷审查要求（征求意见稿）》意见**

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| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
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