# MCN PROCESS OVERVIEW

The United State Food and Drug Administration (FDA) enforces the advertising and promotion of medical devices. The first and most obvious way it does so is by reviewing labeling and other publicly disseminated materials.

Marketing, promotional, and educational materials created and used by ZOLL® to promote products and services must undergo the **MCN approval process** to ensure they adhere to FDA guidance.

## MCN stands for marketing control number.

The MCN process ensures materials are reviewed by director- and VP-level management marketing teams to ensure factual accuracy as well as compliance with regulatory and clinical affairs (if applicable) and other factors.

Each approved project is assigned a unique code, known as an MCN number, to indicate that it has been reviewed and is ready for distribution and use.

The MCN process represents part of ZOLL's Standard Operating Procedure 5002-0064:

### 6.5 Product Literature

New and revised product literature, which is related to device specifications and bears a ZOLL Part Number, is reviewed initially by the product's Marketing Director (or delegate) and the Vice President of Marketing (or delegate), Vice President of Clinical and Scientific Affairs (or delegate) (for whitepapers, CEs and pieces of clinical nature). After the necessary changes and corrections are made, the document is submitted for copy review and approval, following the process that we describe in this document.

### 6.6 Marketing: Digital, Product and Sales Literature

New and revised Advertising and Sales Literature are reviewed as described in the Marketing Material Approval Process (APPENDIX B).

## Breaking down the MCN code

Each part of an MCN number represents a different piece of information. Understanding this formula helps you determine when a piece was produced.

| | Market designation (e.g., H = hospital, P = public safety, I = international) | Type of content (e.g., P= promotional; T = training) | Two digits for year & two digits for month | Control number | Number designating language |
|---|---|---|---|---|---|
| MCN HP 1902 0349 | **H**ospital | **P**romotional | 1902 (Feb. 2019) | 0349 | - |
| MCN IP 2003 0423-11 | **I**nternational | **P**romotional | 2003 (Mar. 2020) | 0423 | 11 (Italian) |
| MCN ET 2203 0012 | **E**MS | **T**raining | 2203 (Mar. 2022) | 0012 | - |

# MCN PROCESS OVERVIEW

## Why we need MCN

The FDA enforces the advertising and promotion of medical devices in a variety of ways. It can obtain advertising and promotional materials from any source or by any means, such as reading product web pages and surfing the internet to learn how consumers use devices.

FDA compliance reviewers attend tradeshows, scientific meetings, and medical conferences; read periodicals; and inspect company facilities.

Advertising and promotional materials shall be "fairly balanced," giving healthcare professionals and consumers a complete and accurate picture of the product.[1]

The MCN process is equally important to our international marketing efforts. The MCN review ensures that ZOLL remains compliant with the regulations of international health authorities, such as the European Union and Heath Canada, for example.

### The FDA and Federal Food, Drug, and Cosmetic (FD&C) Act define advertising and labeling in the following manner:

1. Advertising

    a. Advertising information, other than labeling, which originates from the same source as the product and that is intended to supplement, explain, or be textually related to the product (e.g., print advertising, broadcast advertising, electronic advertising— inclusive of internet advertising, statements of company representative)

2. Labeling

    a. The FD&C Act defines labeling as all labels and other written, printed, electronic, or graphic matter:

        i. Upon any article or any of its containers or wrappers

    b. The term "accompanying" is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, filler, etc.

    c. "Accompanying" also includes labeling that is brought together with the device after shipment in interstate commerce.

## What is a claim?

*A factual (product) claim* is any statement of fact regarding a ZOLL product or service that's intended to be read by an end user, customer, or prospect. Claims must be established as true and provable via cited research or other documented evidence as determined by the MCN review.

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## Violative materials

In general, materials that contain the information listed below are considered violative, or non-conforming, and don't comply with the relevant rules and laws:

- Claims that compare the product to another product without any specific proof
- Claims that a product is safer or more effective than its labeling indicates
- Misrepresentation of a study or other information pertaining to clinical data
- Use of graphics or other framing material in a misleading way
- Use of a badly designed study to support a claim
- Misrepresentation of statistics

## What materials require MCN review?

Any material that includes a factual product claim concerning a ZOLL product, service, or technology must undergo MCN review and approval. That includes but is not limited to:

- Marketing materials (including but not limited to brochures, flyers, eblasts, mailers, postcards, direct mail, print ads, videos, web content, social media posts, trade show materials, etc.)
- Internal training materials (including e-learning)
- Clinical articles and white papers
- iPad and Android apps

## MCN review and non-English language or translated materials

- An English-language version of any foreign-language content must be provided for the MCN approval process.
- If an MCN-approved English-language document is translated into another language, it must undergo "linguistic review" to ensure all meanings and contexts are consistent with the English-language version.

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## MCN approval process

A project advances through established tiers of reviewers as it is marked "Approved" or "Approved with Changes."

If any reviewer marks the project "Change and Resubmit," the process stops. The project must be resubmitted with the requested updates or changes and the process begins again.

### TIER 1

- Requestor
- Director of marketing/channel
- Director of international marketing (if applicable)
- Director of global product management (for technical product info, if applicable)
- Director of global sales training (for internal training materials)
- Clinical affairs (for whitepapers, CEs, and clinical studies)

### TIER 2

- VP of marketing
- VP of QA/RA and/or director of RA

### TIER 3

- Requestor

### TIER 4

- IMS editorial team member

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## What do MCN reviewers look for?

Reviewers look for risks and benefits to be fairly balanced and try to ensure that the product or service is represented in such a way that accurately reflects the approved uses and claims.

"Fairly balanced" is an overall net impression. A promotional piece needs to have a balanced presentation of both the benefits and the risks of a product.

Fair balance includes, but is not limited to, product information about warnings, precautions, contraindications, email correspondence with healthcare professionals, and any special product considerations.

## Commonly asked questions about MCN review

**Q:** *This claim has been used a million times before. Does my project still need MCN if I know the claim is true?*
**A:** Yes. The claim must be reviewed each time it's used to ensure it's used in the appropriate context.

**Q:** *A claim has been approved through the MCN process and I'd like to add it to an existing, previously approved marketing piece. Does the previously approved marketing piece need to go back through MCN when this approved claim is added?*
**A:** Yes. Adding an approved claim from one piece of marketing collateral to another creates a new piece of collateral that requires a new round of MCN review.

**Q:** *This marketing collateral has already been MCN approved. Do I need to check my facts and citations when I request an update to copy or images?*
**A:** Yes. Facts and claims must be checked each time a project is submitted. URLs break, websites reorganize their content, and citations become outdated. It's important to confirm readers can access your citations and references each time you cite them, even if the citations themselves haven't changed.

**Q:** *Do I need MCN if my marketing collateral will only be used internationally?*
**A:** Yes. Regardless of where collateral is distributed, product claims must be reviewed to ensure they're accurate. If a document includes a product claim, it needs MCN review.

**Q:** *What should I do if I'm not certain whether an asset requires MCN review and approval?*
**A:** Ask! Please check with Elizabeth Haines or IMS project management. When in doubt, ask for your project to go through MCN review.

# MCN PROCESS OVERVIEW

## Commonly asked questions about MCN review (cont.)

**Q:** *How can I help move my projects through MCN efficiently?*

**A:** Always provide complete background information. Complete the MCN questions on the InMotion project request form to help the reviewers understand the scope of your project and marketing initiative.

i. Who requested this project?
ii. Who is the target audience?
iii. What is the goal of the project?
iv. How will this piece be used? (Eblast, social, print, website, video, etc.)
v. Where will this piece be used? (US, North America, EMEA, APAC, LATAM, global, etc.)
vi. Who has reviewed this project prior to this MCN review?
vii. If you are updating an existing piece, what has changed?
viii. Does this project include content from another previously approved MCN? If so, what is MCN number of that piece and when was it approved?

Be prepared to collaborate. Thoroughly review all information submitted prior to MCN and collaborate with necessary parties (management, product expert, etc.) to ensure your submission is complete before you begin the MCN process.

**Q:** *When planning project timelines, how much time should we anticipate the MCN process will take?*

**A:** While there is no set timeframe for MCN, we recommend that you include one to two weeks for the review process. Pieces with detailed background information or those where the project requestors directly follow-up with MCN reviewers seem to move through the MCN review process more quickly.

**We try to make the process as efficient as possible by:**

- Asking reviewers to complete their reviews in a timely manner
- Sending automated reminders to reviewers every 3 days

**Q:** *Do MCN numbers expire?*

**A:** MCN numbers DO NOT expire. However, updating an existing piece with new claims creates a new unique piece of collateral. That new piece gets a new MCN number to replace the old MCN number. This also maintains version control.

[1] "MCN Fireside Chat: Questions & Answers" PowerPoint presentation by ZOLL Quality, Regulatory, and Service Department, March 2022.