

# **Considerations for Whether Marijuana Has a Currently Accepted Medical Use in the United States for Purposes of Section 202(b) of the Controlled Substances Act**

**Report prepared by the Food and Drug Administration's Center for Drug  
Evaluation and Research (CDER), by personnel located in CDER's:**

**Office of the Center Director's Controlled Substance Staff**

**and**

**Office of Surveillance and Epidemiology's Office of Pharmacovigilance and  
Epidemiology, Division of Epidemiology I**

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## Glossary

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# I. Executive Summary

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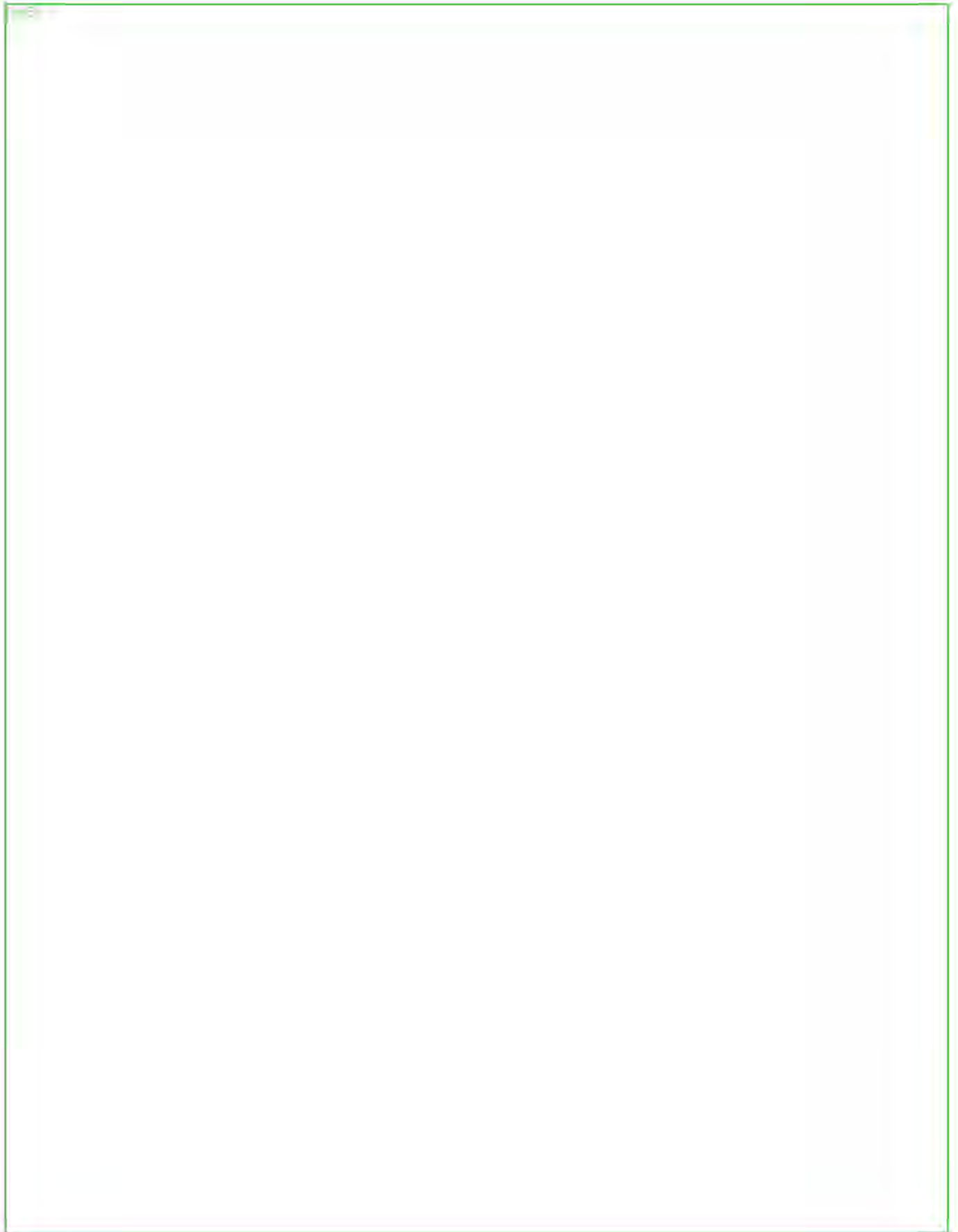
## 1. Background

The Department of Health and Human Services (HHS) has conducted an evaluation of whether marijuana<sup>1</sup> has a “currently accepted medical use in treatment in the United States” (CAMU) for purposes of scheduling under the Controlled Substances Act (CSA), 21 U.S.C. 812(b). Such an evaluation is one of the findings relevant to the placement of a substance in one of five drug control “schedules” set forth in 21 U.S.C. 812(b).

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<sup>1</sup> See Section II.2.









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## II. Evaluation of Marijuana with Respect to CAMU

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### 1. Introduction

Drugs or other substances with abuse potential are placed into one of five schedules (i.e., Schedule I, II, III, IV, or V) under the federal Controlled Substances Act (CSA) based on whether the drug has a currently accepted medical use in treatment in the United States and its degree of abuse and dependency potential. Collectively, drugs and other substances listed among the five drug schedules are controlled substances under federal law and are subject to the federal regulatory requirements of the Drug Enforcement Administration (DEA), where regulatory requirements may vary relative to each of the five drug control schedules. Stricter regulatory controls are associated with schedules that are for those substances posing the greatest harms to public health, i.e., substances controlled under Schedule I and II which have a high potential for abuse and greatest safety concerns and potential to cause severe psychological and/or physical dependence. Specifically, drugs controlled under Schedule I have a high potential for abuse but do not have a currently accepted medical use, whereas drugs controlled under Schedule II have the same high potential for abuse but have a currently accepted medical use in treatment in the United States (CAMU) or a currently accepted medical use with severe restrictions. Drugs in Schedule III, IV, and V, have a currently accepted medical use, but substances in these schedules have incrementally decreasing degrees of abuse potential and dependence liability, i.e., Schedule V having substances with the lowest abuse potential and dependence liability while still warranting some degree of regulatory controls.

On October 6, 2022, the Biden Administration issued a statement on reforms associated with marijuana,<sup>7</sup> a substance currently controlled in Schedule I of the CSA ([Biden 2022](#)). As part of the statement, the President directed the Secretary of the Department of Health and Human Services (HHS) and the Attorney General to initiate the administrative process to review expeditiously how marijuana is scheduled under federal law. The Secretary requested that the FDA, in consultation with the National Institute on Drug Abuse (NIDA), conduct a scientific and medical evaluation of marijuana that would enable the Office of the Assistant Secretary for Health (OASH), on behalf of the Secretary, to convey recommendations to the DEA regarding the appropriate scheduling of marijuana. A necessary component of the overall scientific and medical evaluation of marijuana for drug scheduling purposes is a finding as to whether marijuana is considered to have a CAMU in the United States under the CSA, where such finding will have implications for the schedule of control that is ultimately recommended by HHS as most appropriate in accordance with 21 U.S.C. 812(b). This document is intended to analyze and present the relevant data and make a determination as to whether marijuana is considered to have a CAMU in the United States under the CSA.

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<sup>7</sup> “Marijuana” as defined in 21 U.S.C. 802(16)

## 2. Definitions Relevant to the Analysis of Whether Marijuana Has a CAMU

Marijuana is a psychoactive drug produced from the *Cannabis sativa L.* plant. Cannabis is one of the oldest cultivated crops, providing a source of fiber, food, oil, and drug, and it contains a variety of chemical compounds, including delta-9-tetrahydrocannabinol ( $\Delta$ 9-THC).  $\Delta$ 9-THC is considered to be the main psychoactive component of the *Cannabis sativa L.* plant; however, the plant is also known to contain other psychoactive cannabinoids.

Marijuana is a subset of cannabis, and the CSA defines marijuana or “marihuana”<sup>8</sup> as:

*(16)(A) Subject to subparagraph (B), the terms "marihuana" and "marijuana" mean all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.*

*(B) The terms "marihuana" and "marijuana" do not include-*

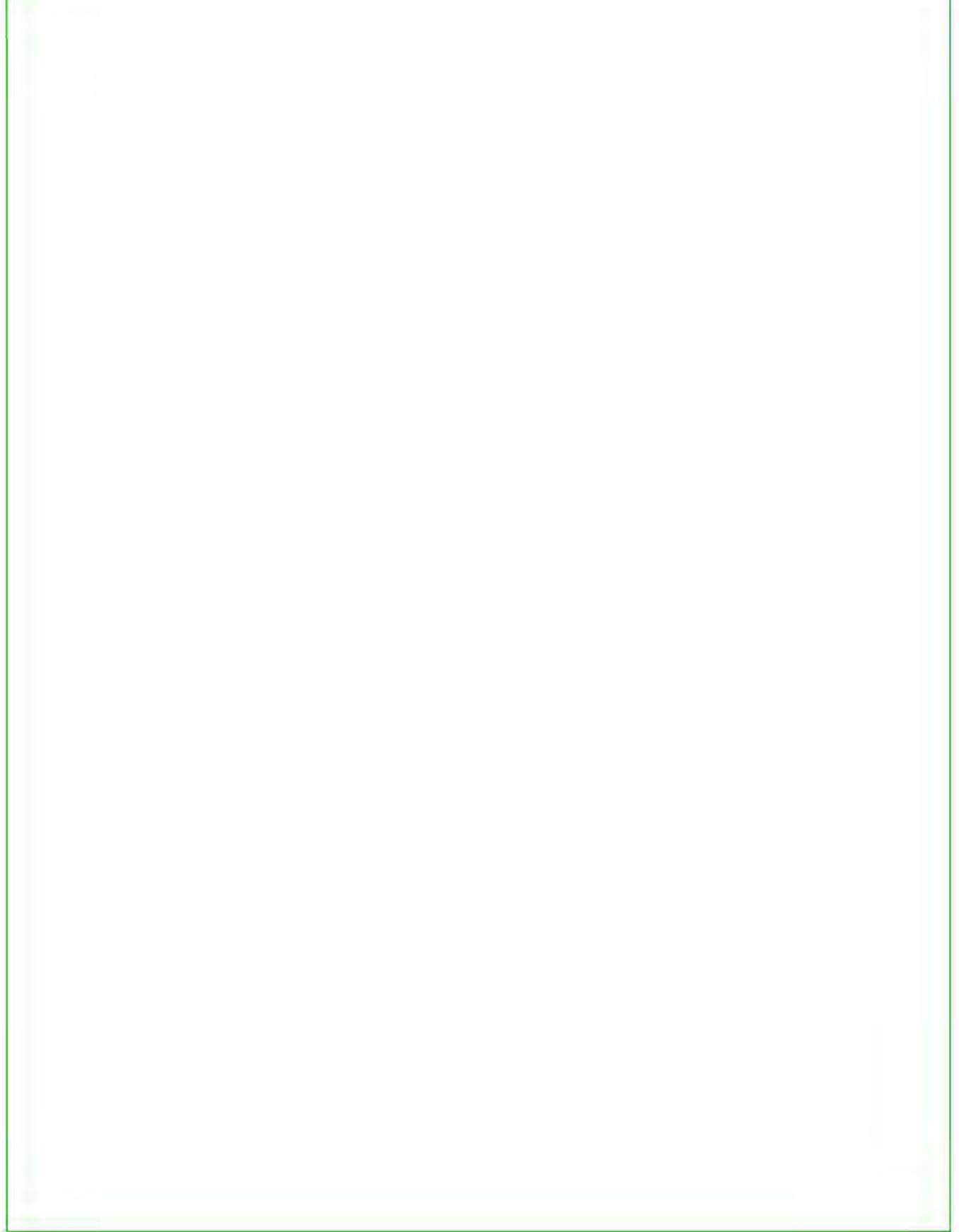
*(i) hemp, as defined in section 1639o of title 7; or*

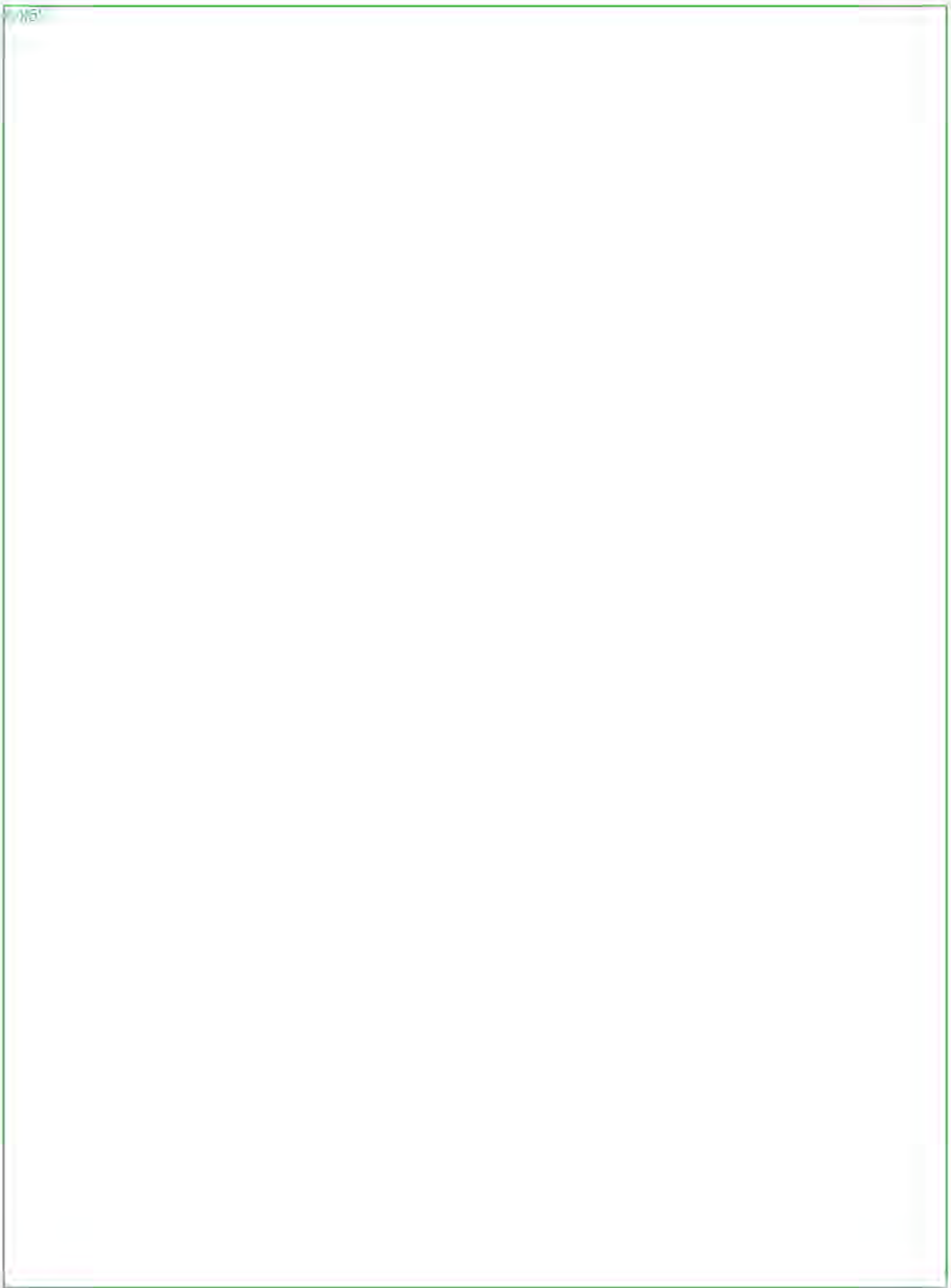
*(ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.*

The exclusion of “hemp”-type cannabis from marijuana’s Schedule I control status reflects the provisions of the 2018 Agriculture Improvement Act (i.e., the “Farm Bill”), which defined hemp as *Cannabis sativa L.* and its derivatives with no more than 0.3 percent  $\Delta$ 9-THC on a dry weight basis, and explicitly revised the definition of marijuana in the CSA to exclude, and effectively decontrol, hemp.

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<sup>8</sup> 21 U.S.C. 802(16)







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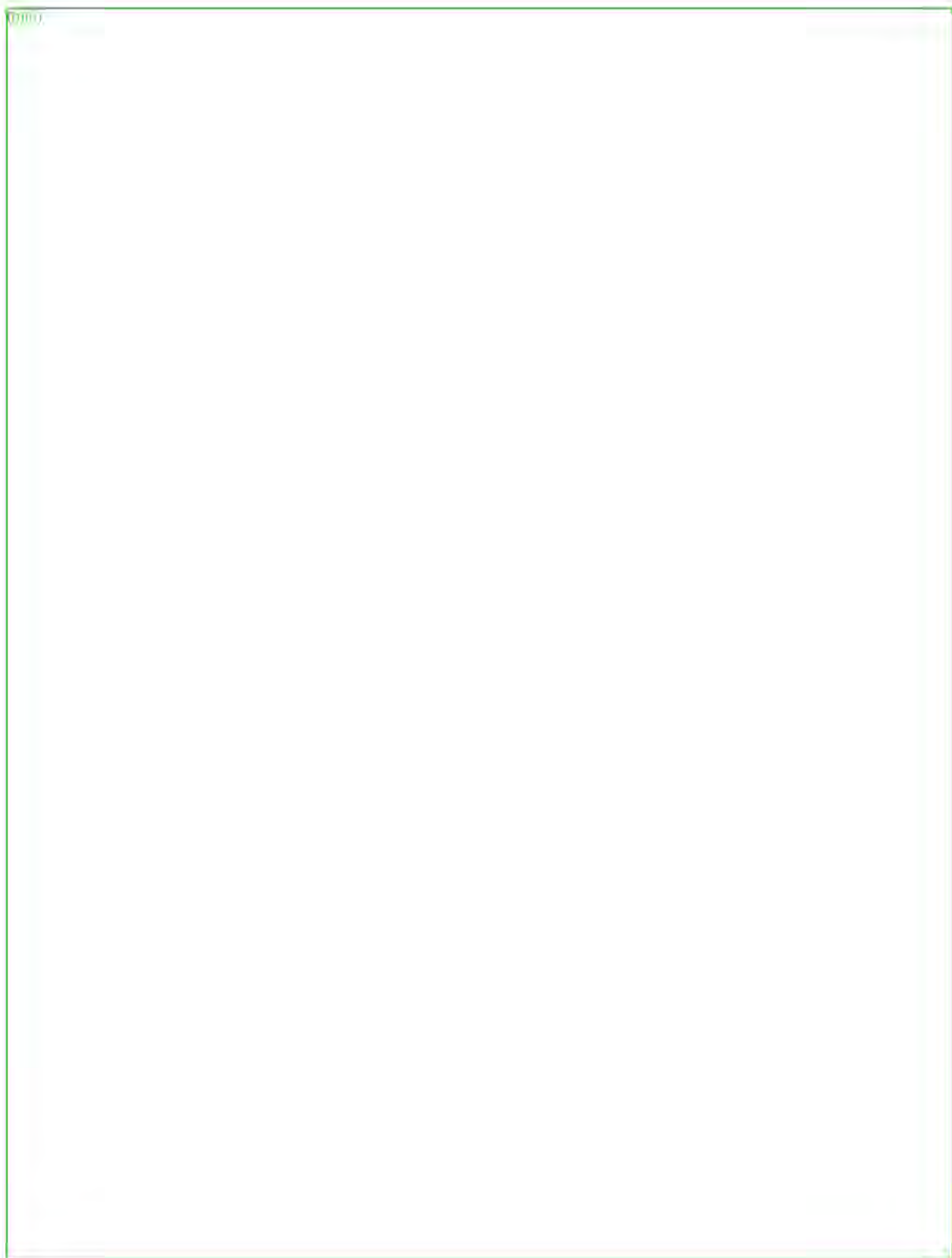












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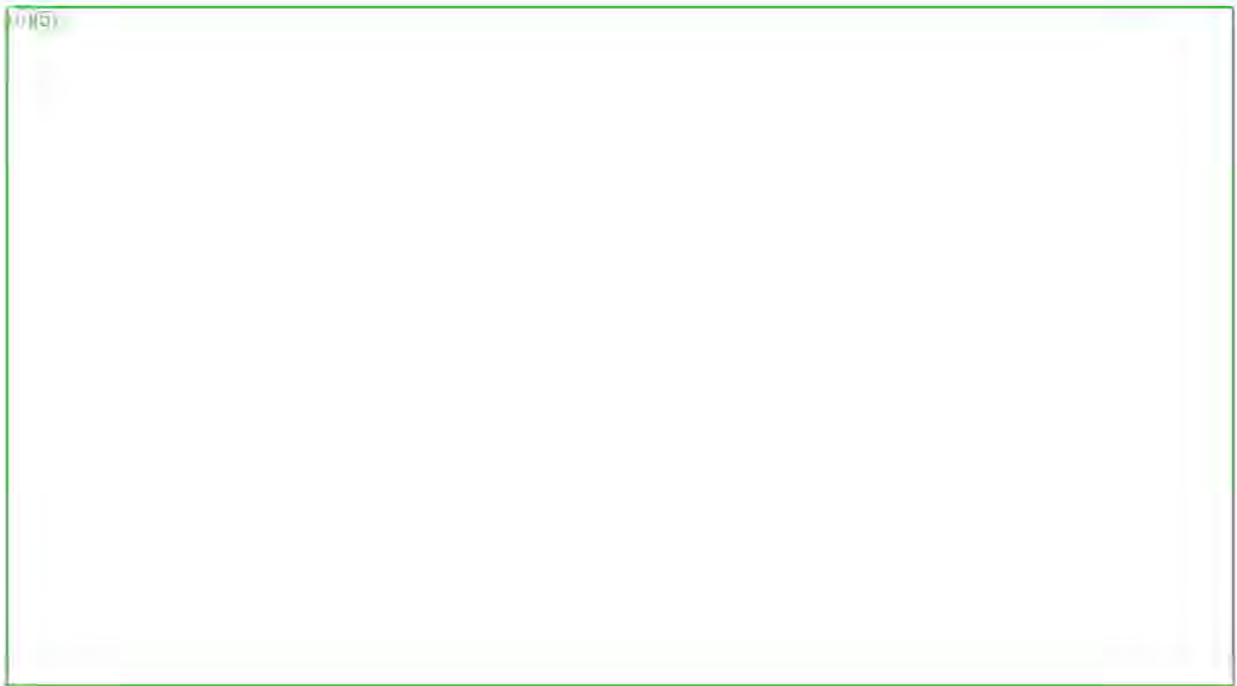


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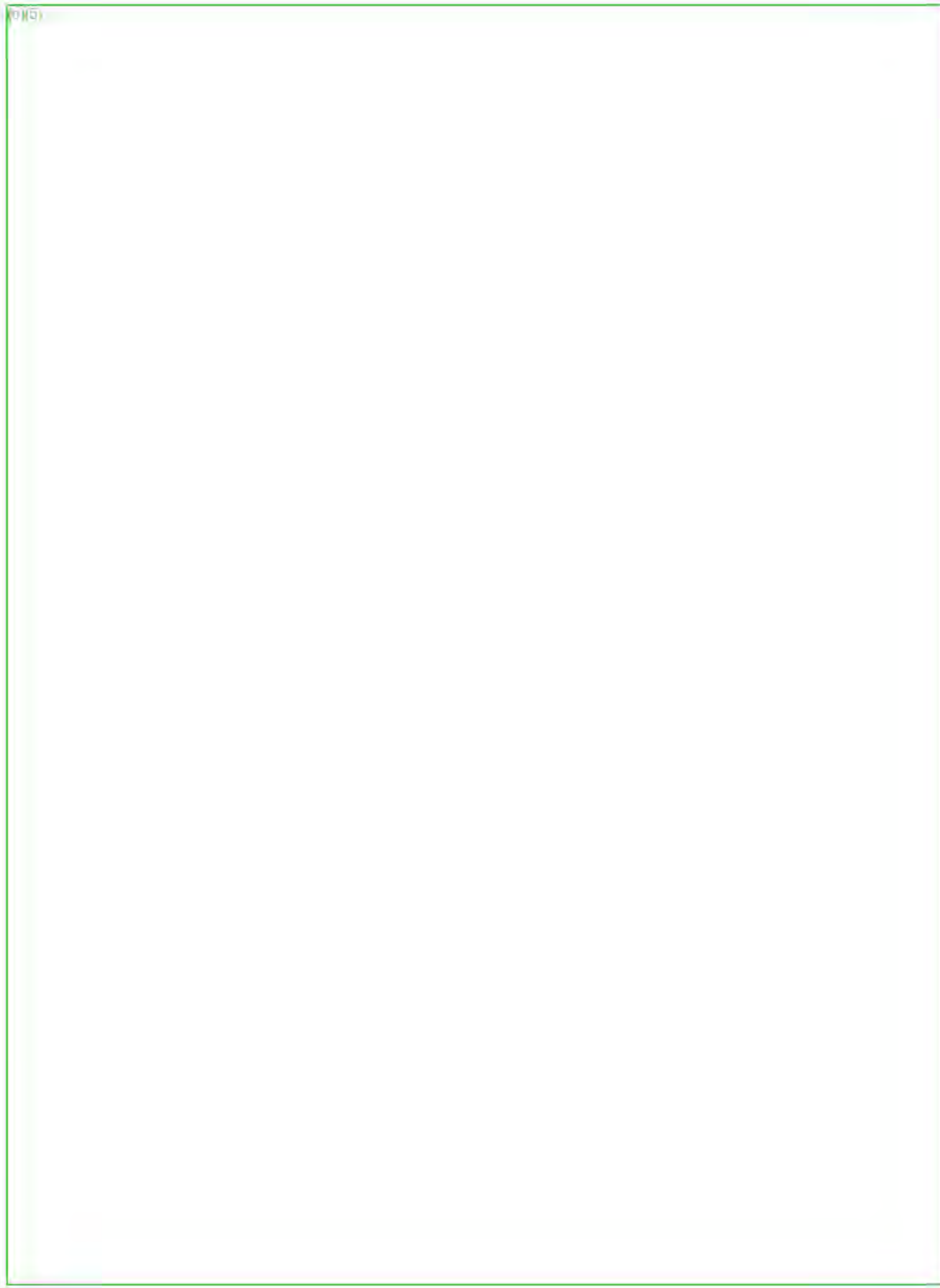
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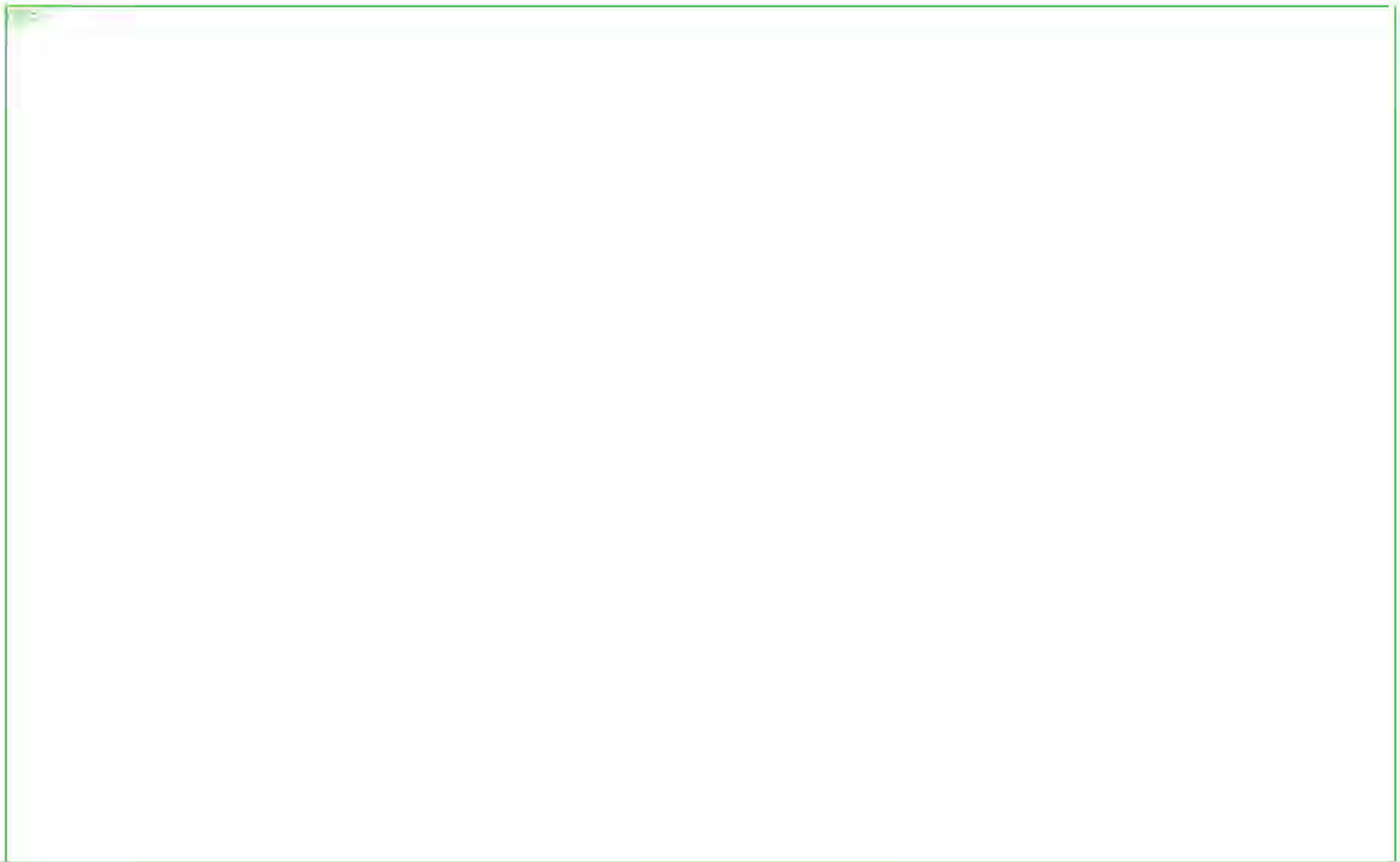


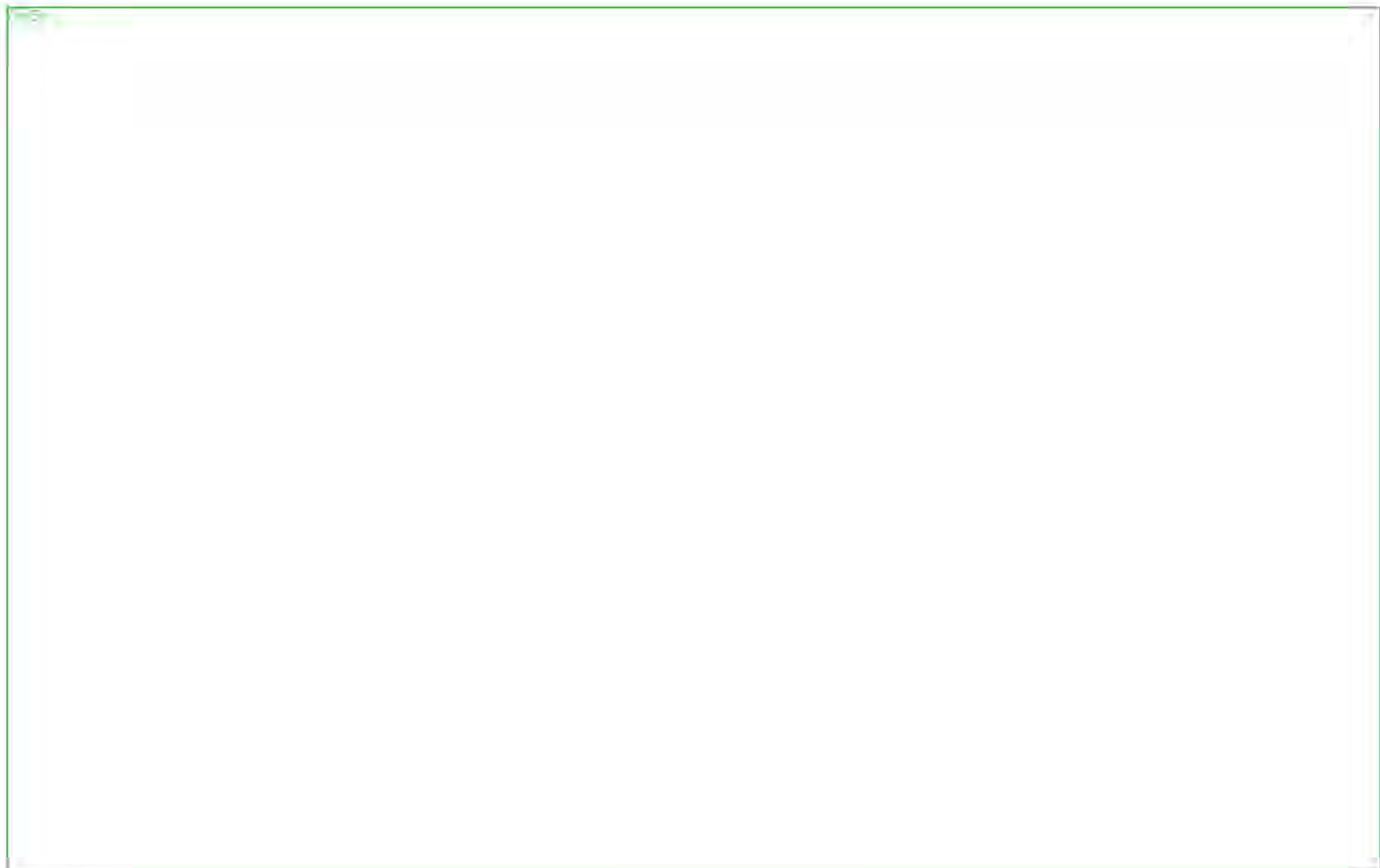




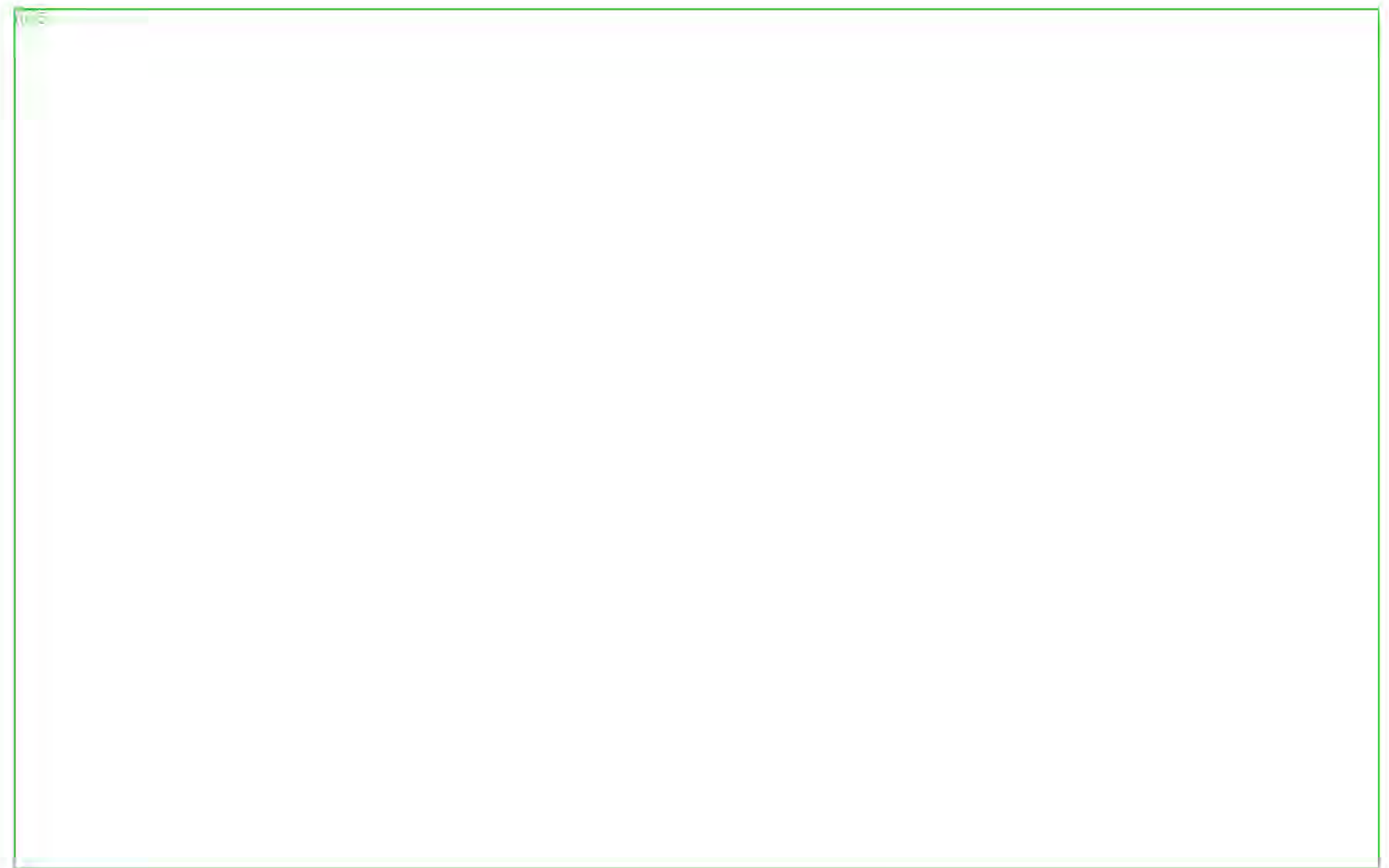
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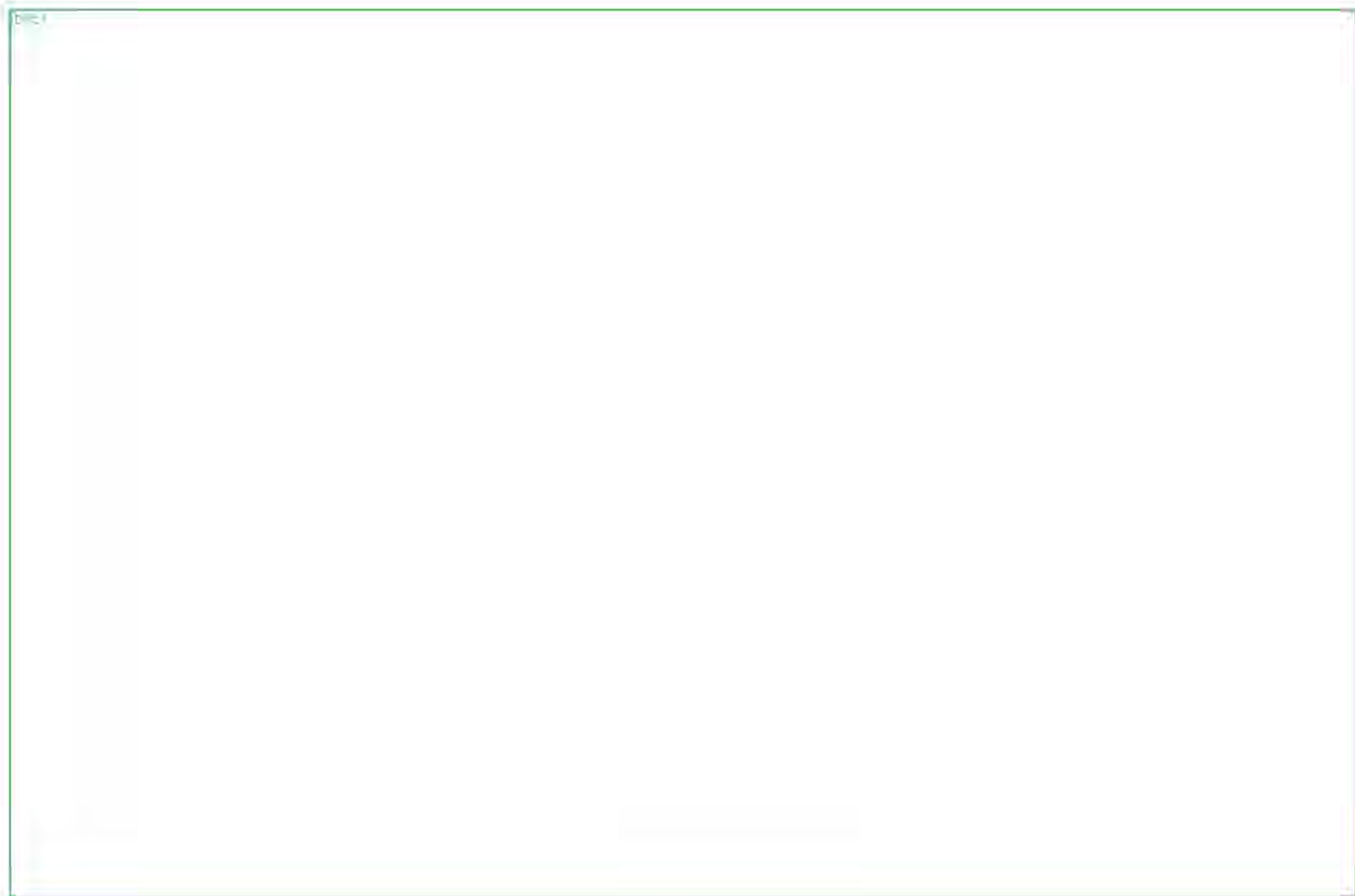






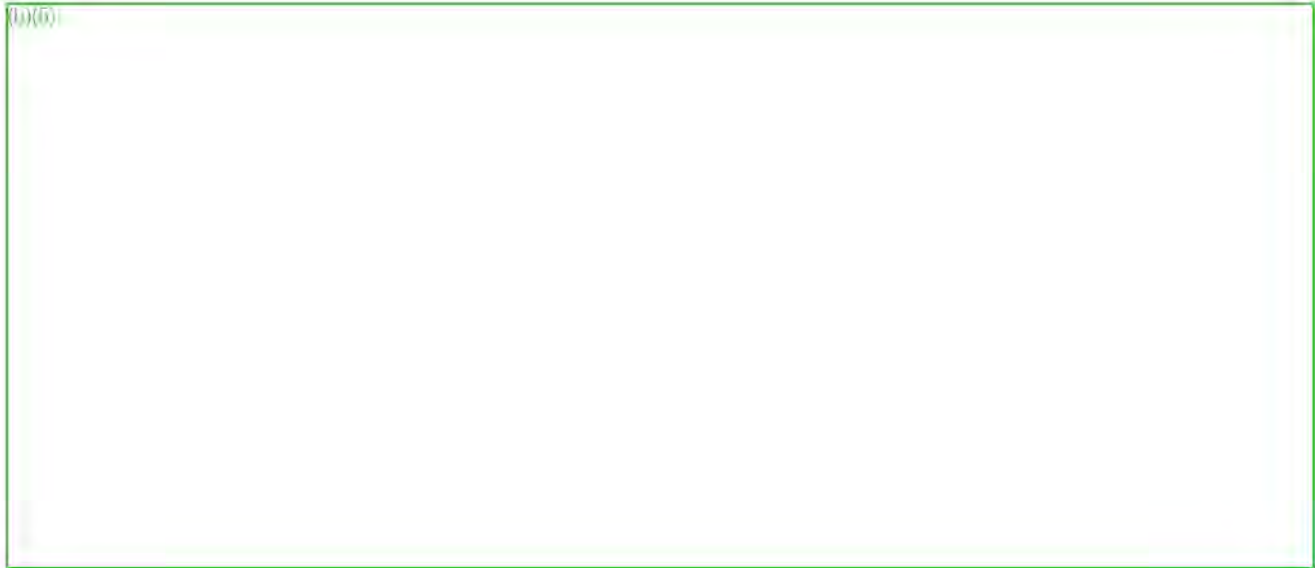








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<sup>20</sup> Two of the eight observational studies were included in other indications (i.e., anorexia and anxiety) as pain was a secondary outcome.









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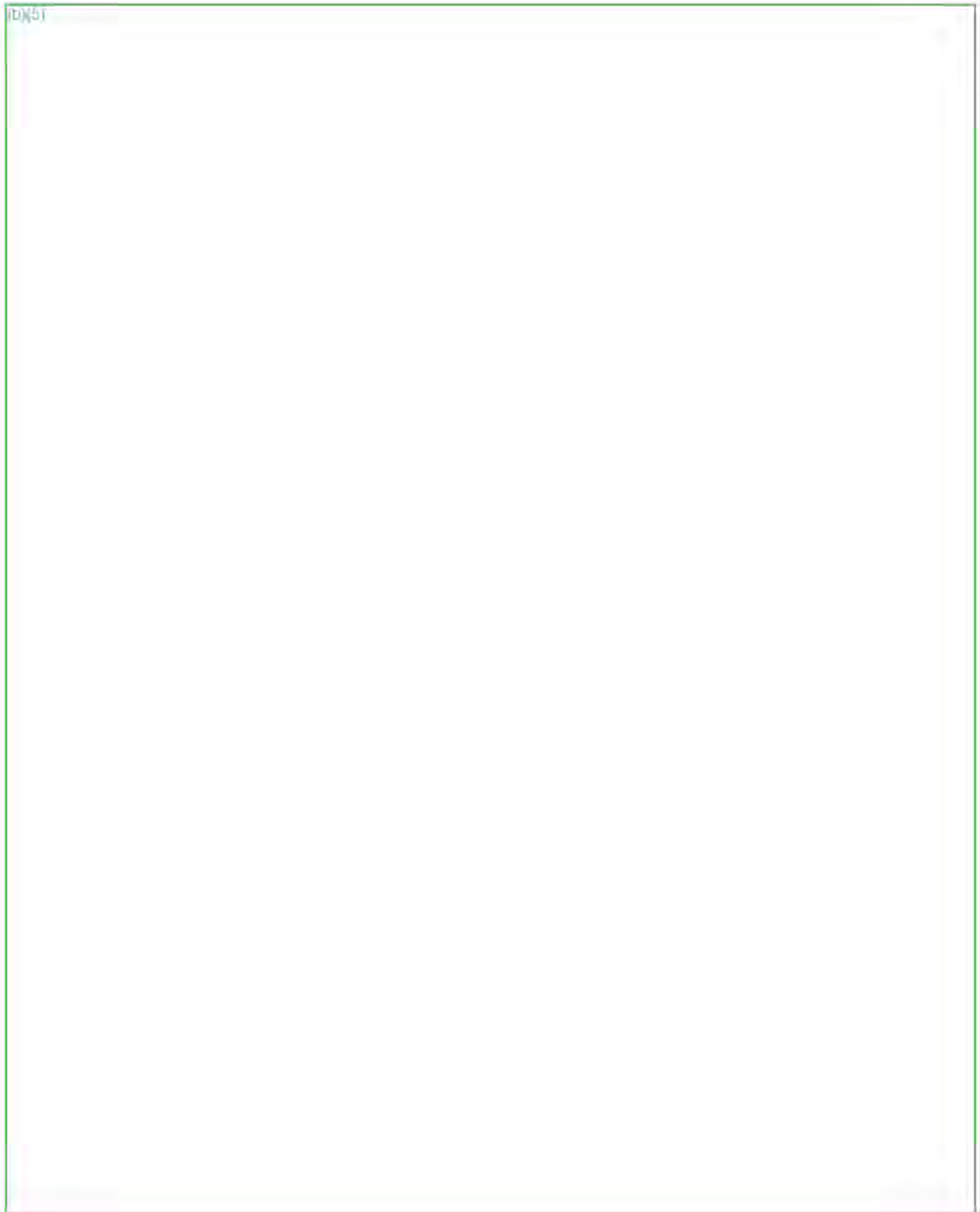


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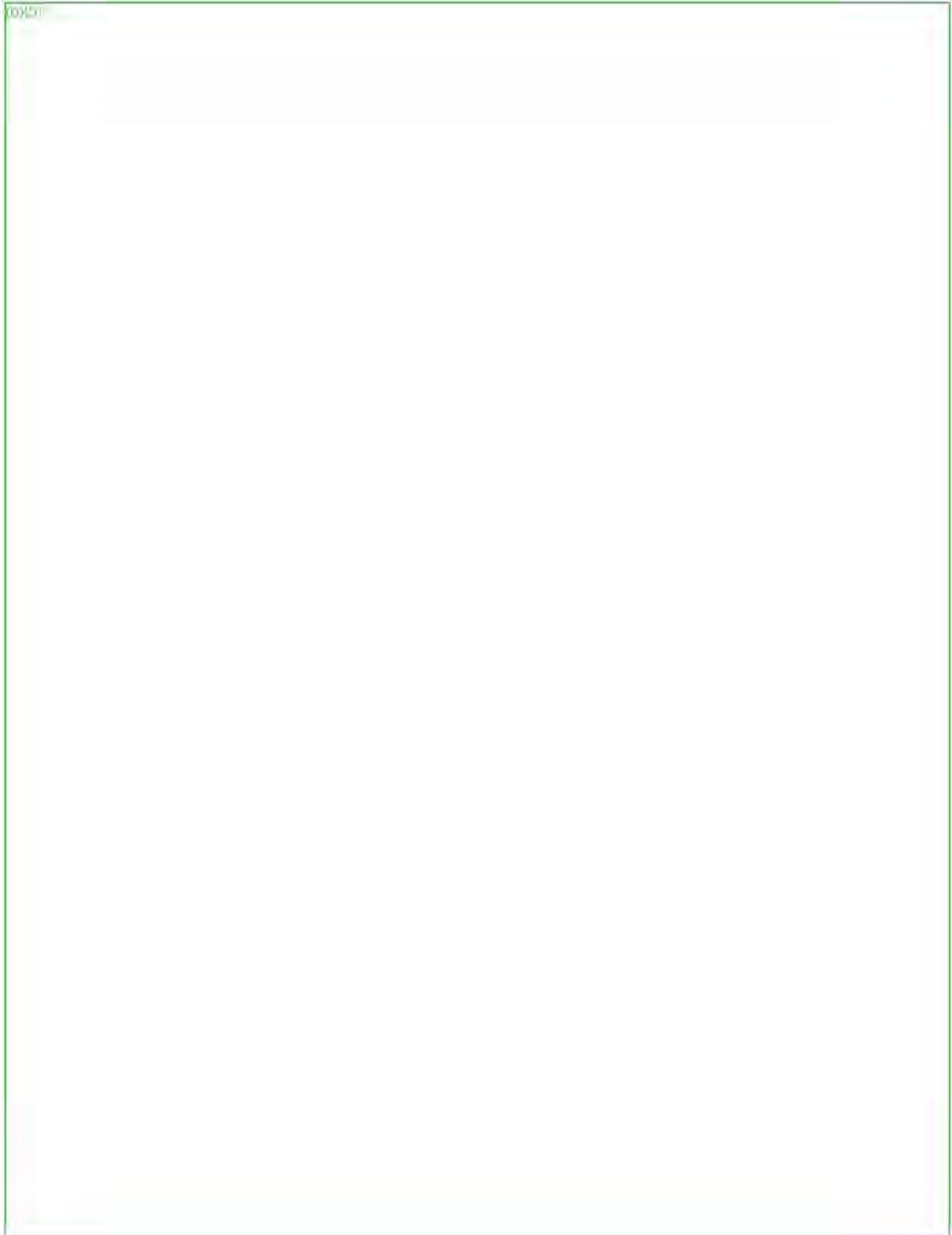


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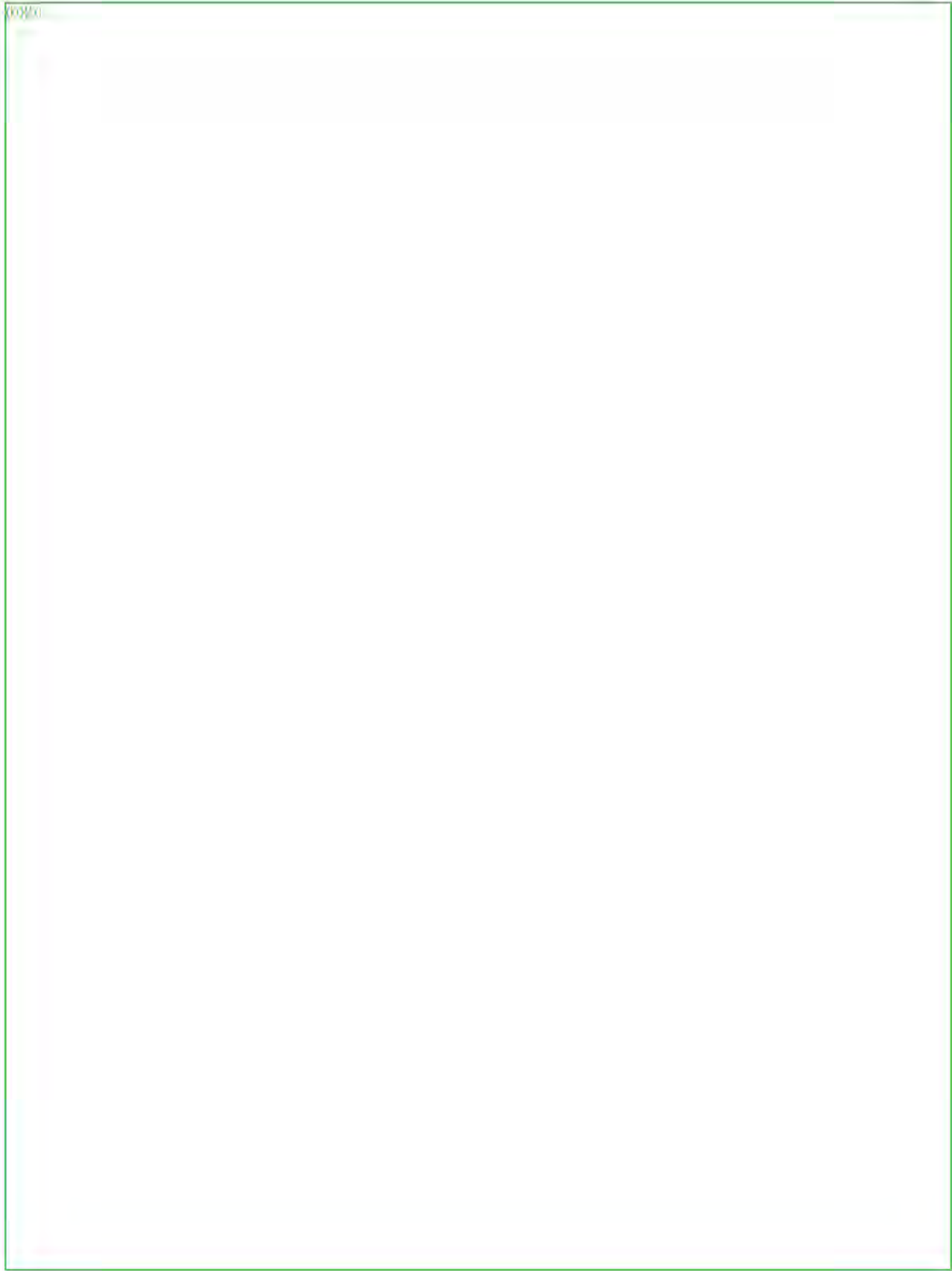




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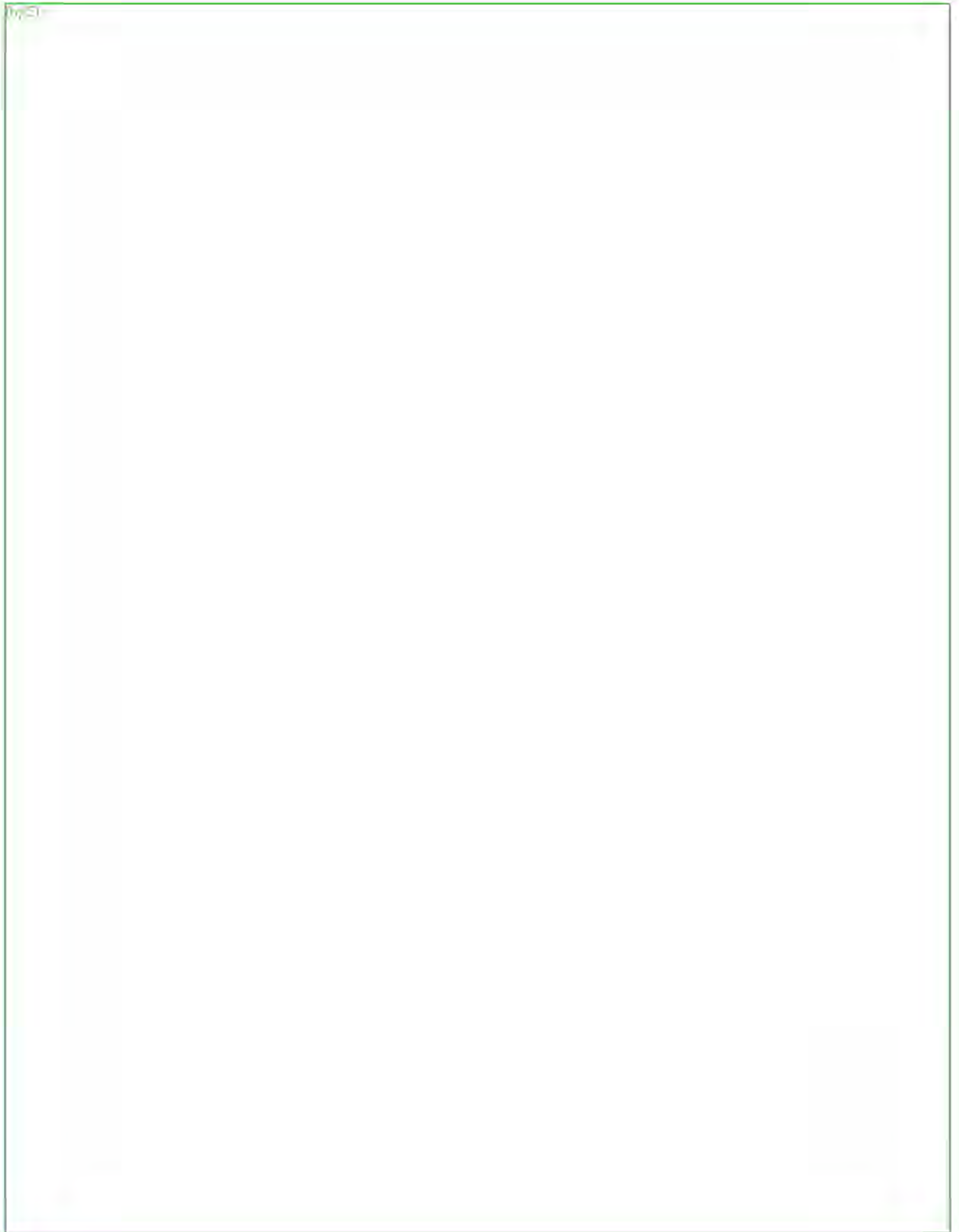


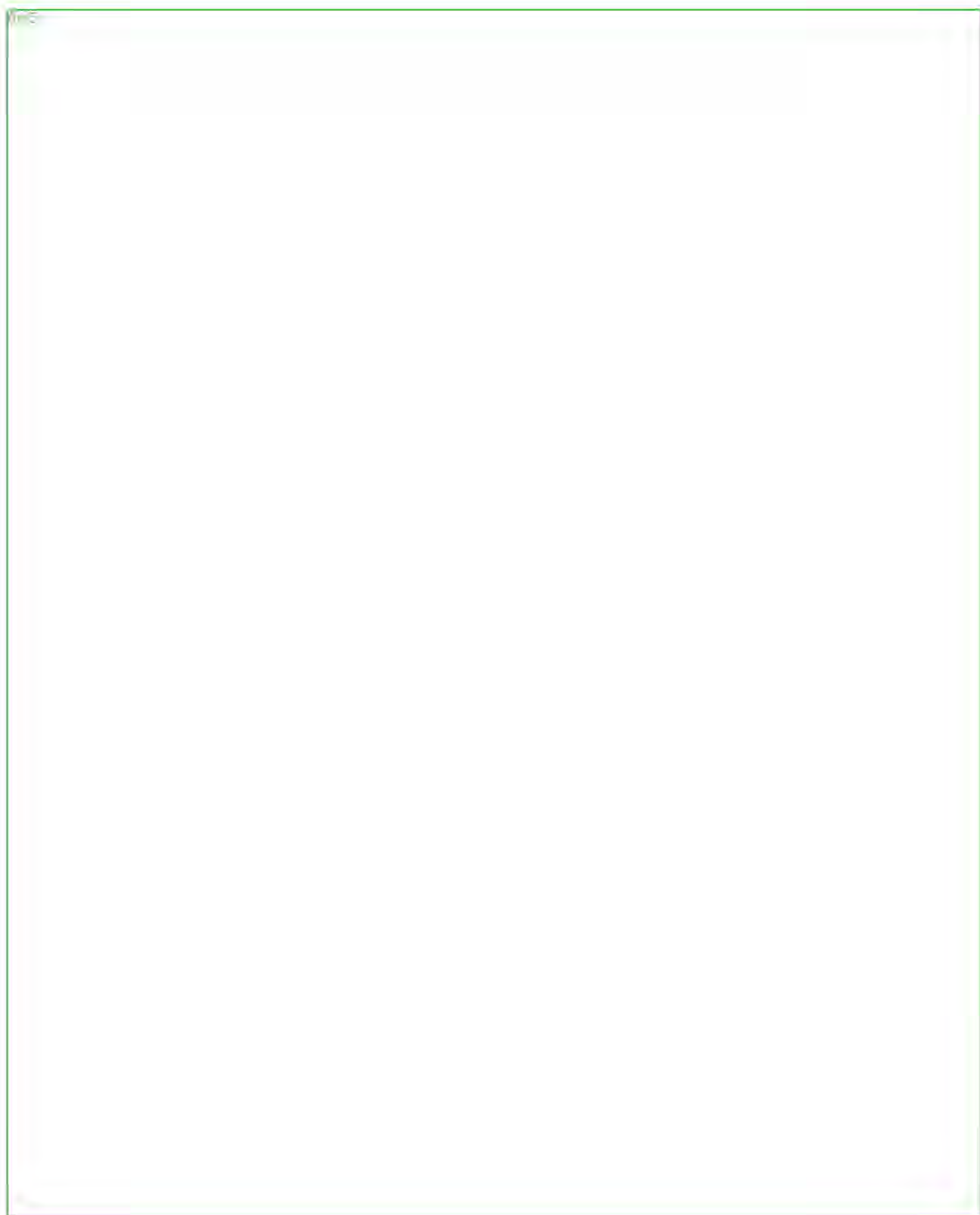
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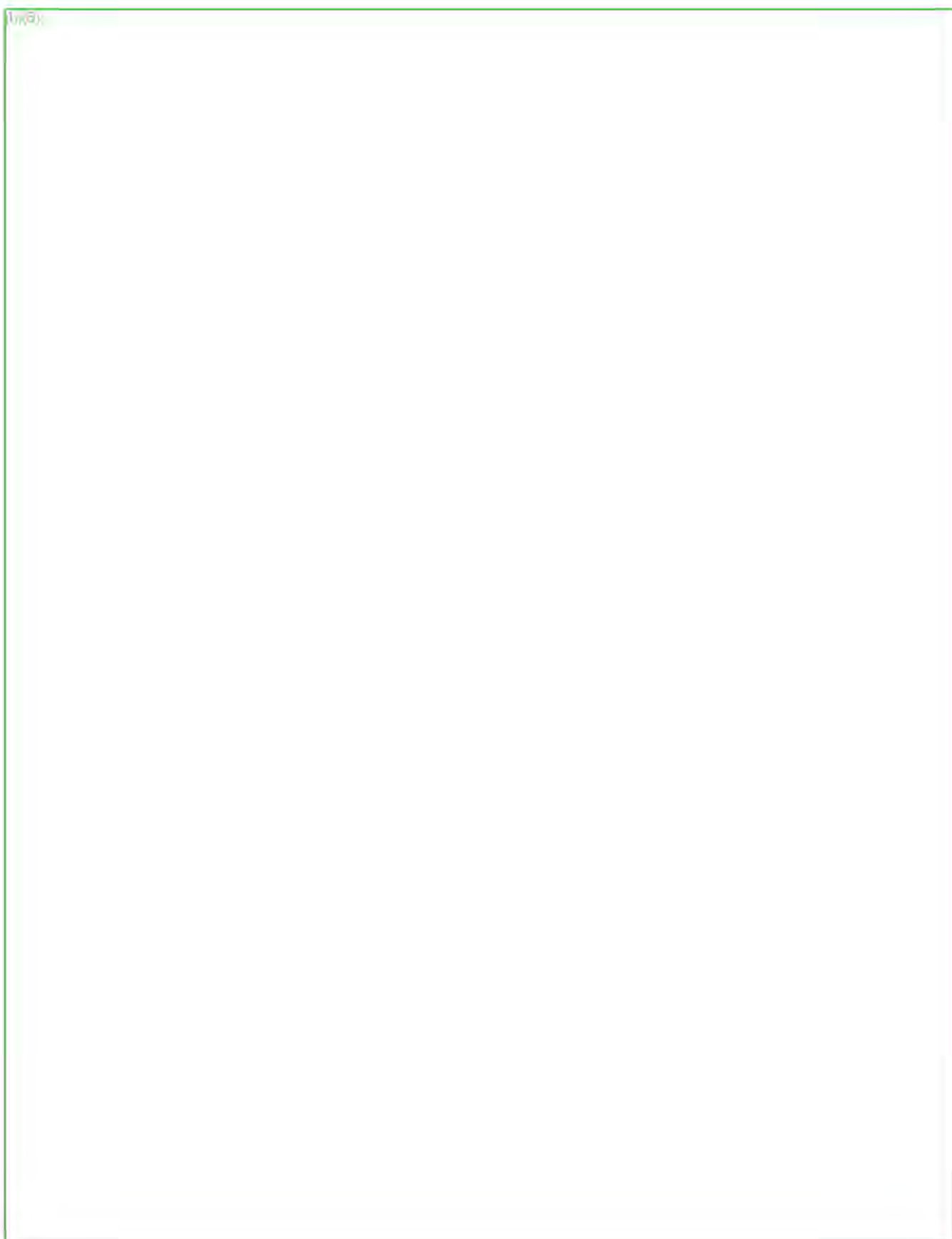
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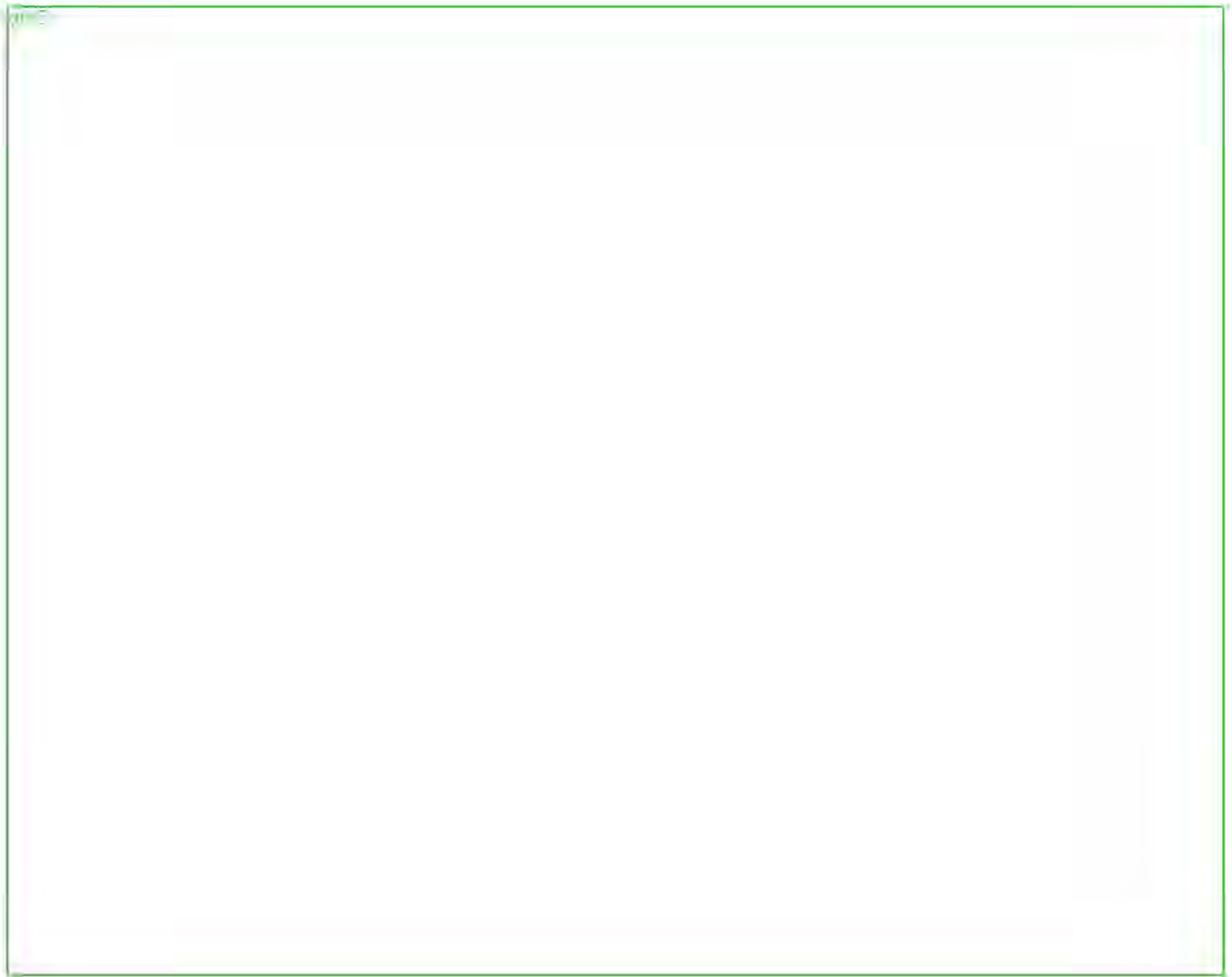












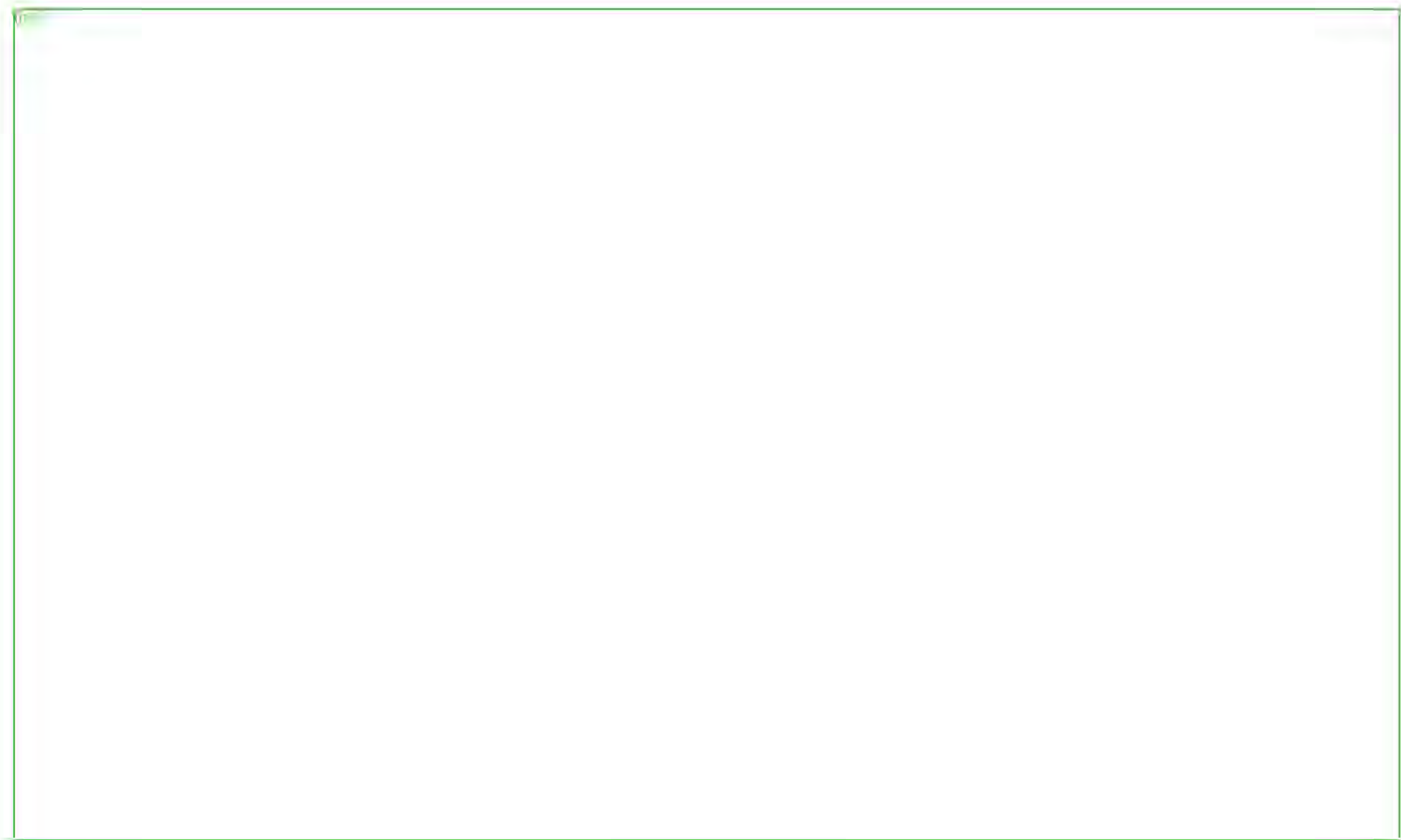


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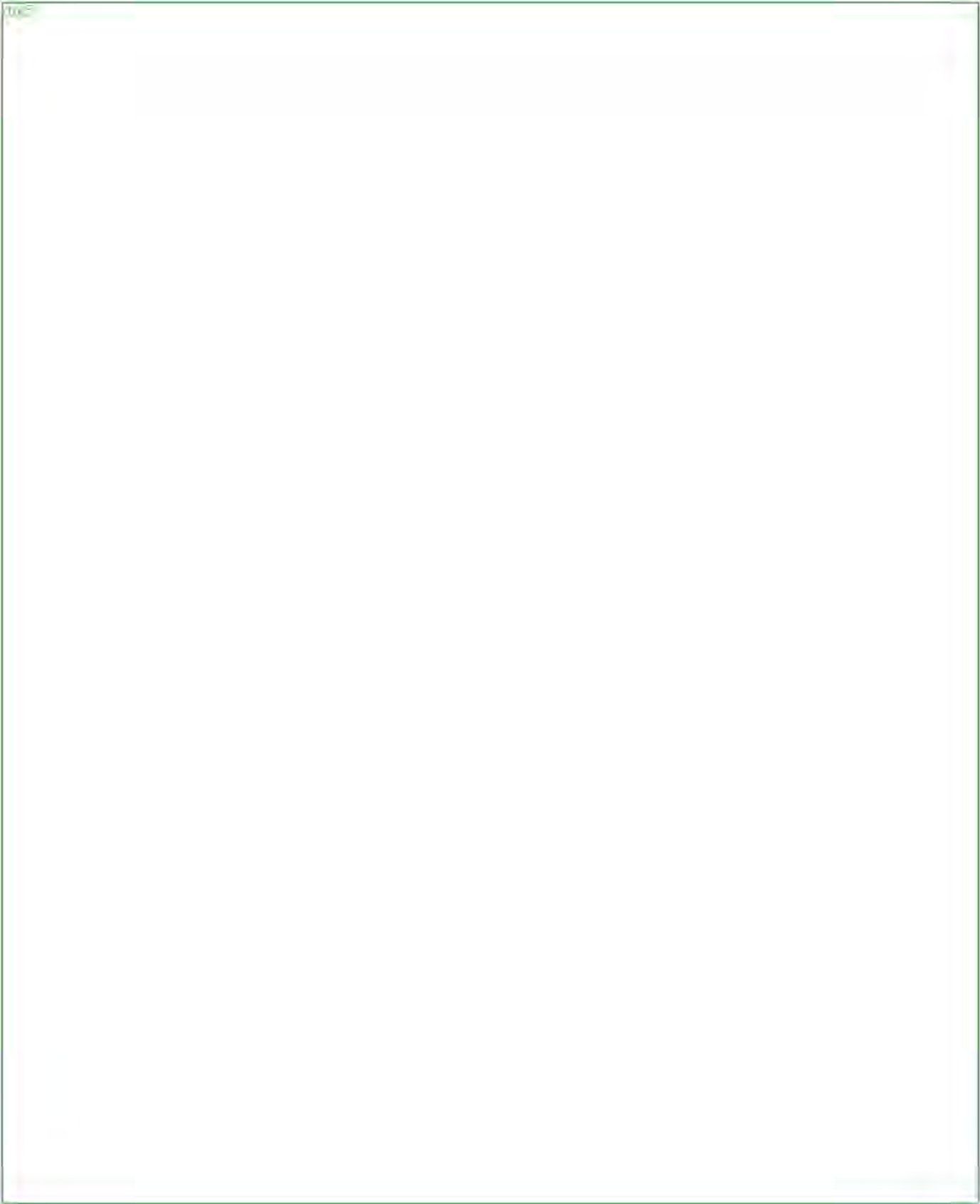


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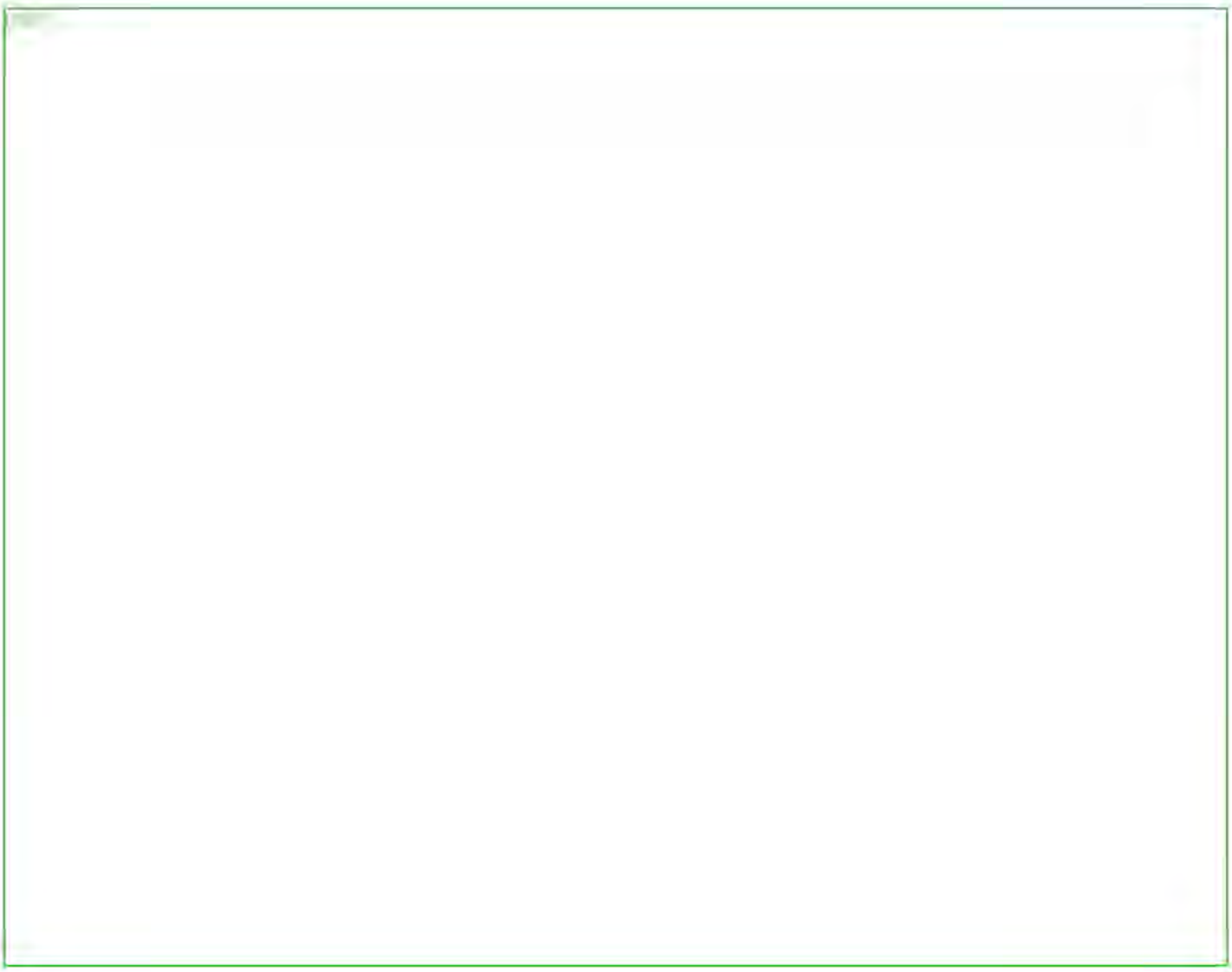
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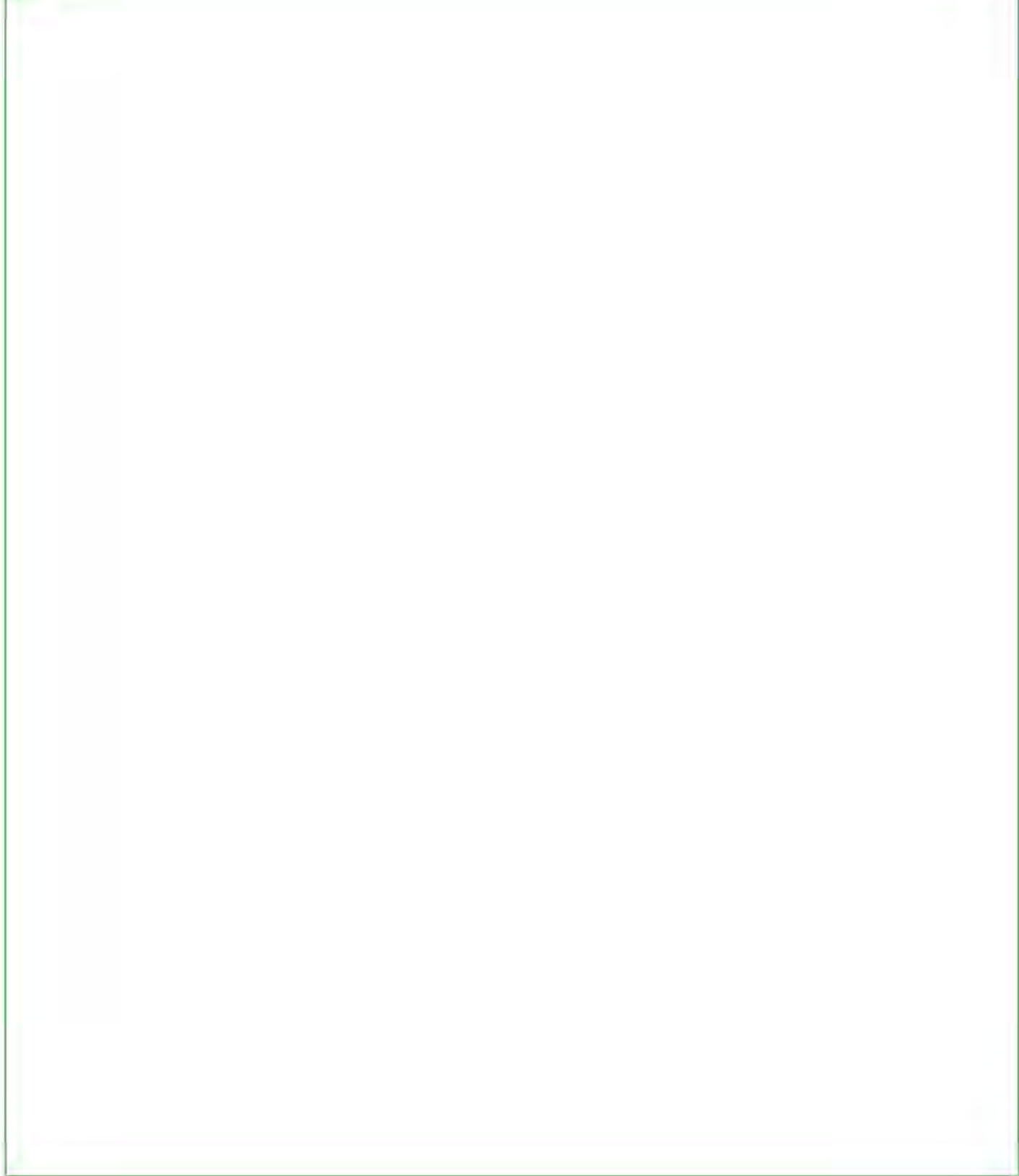


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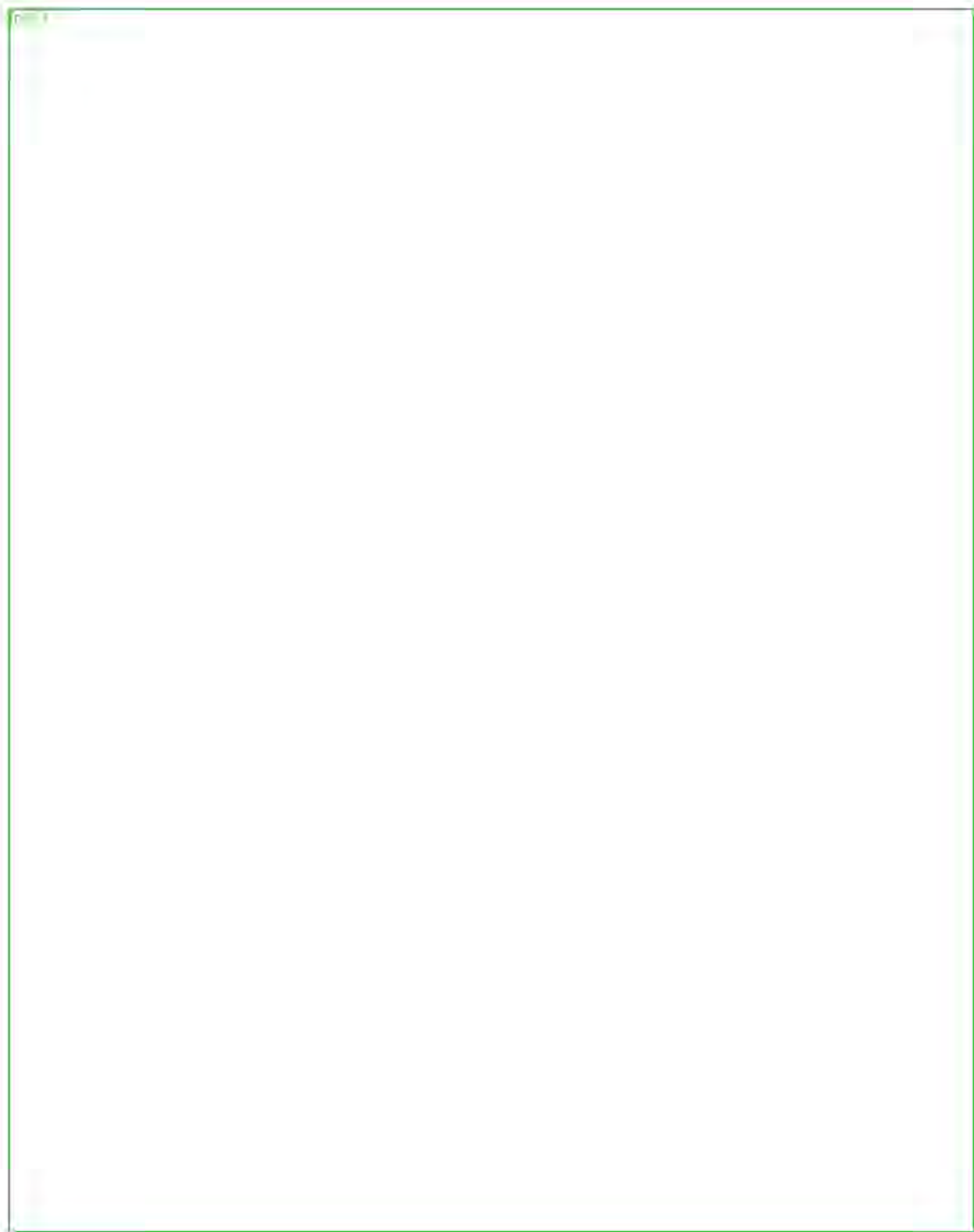




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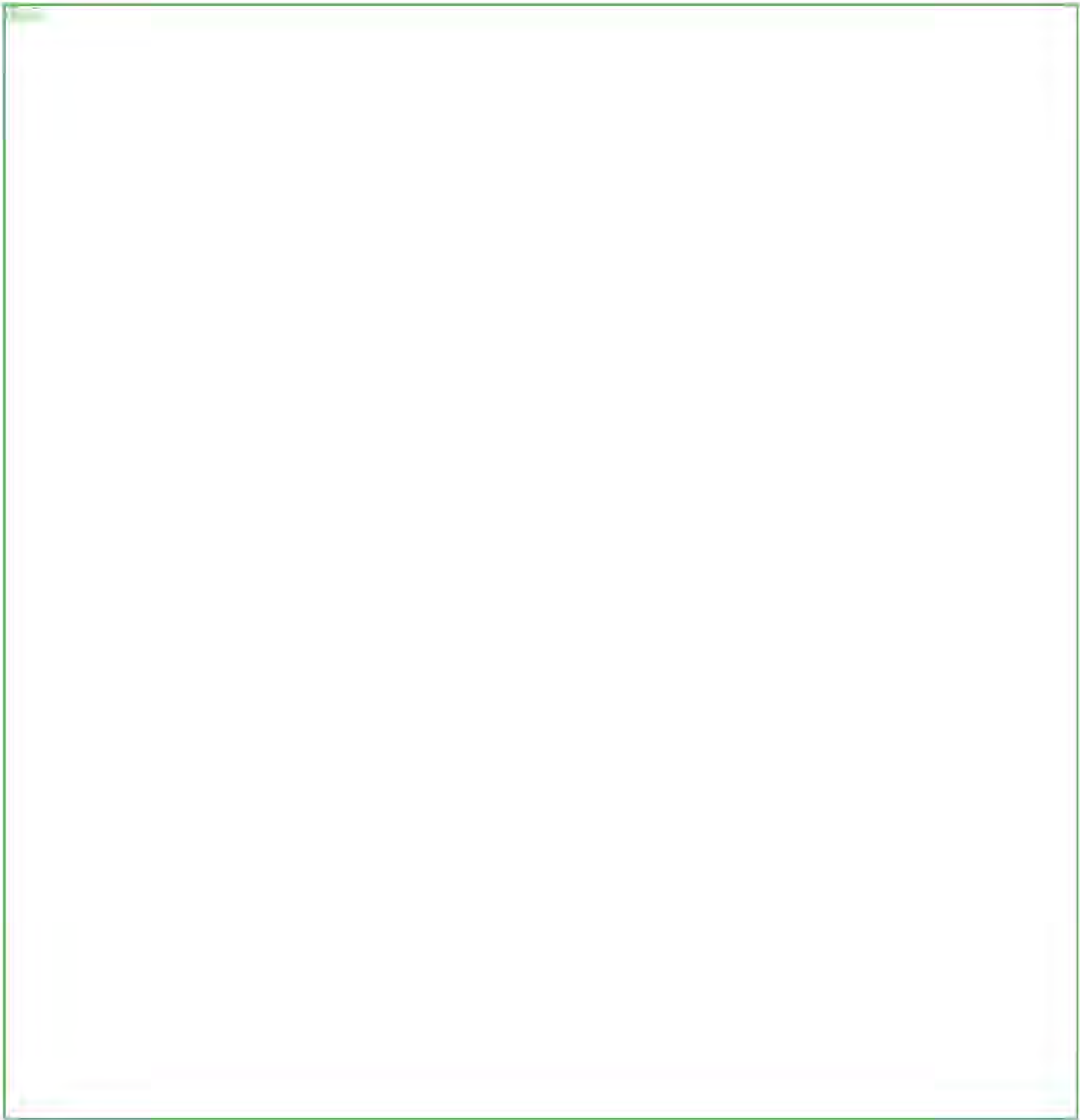






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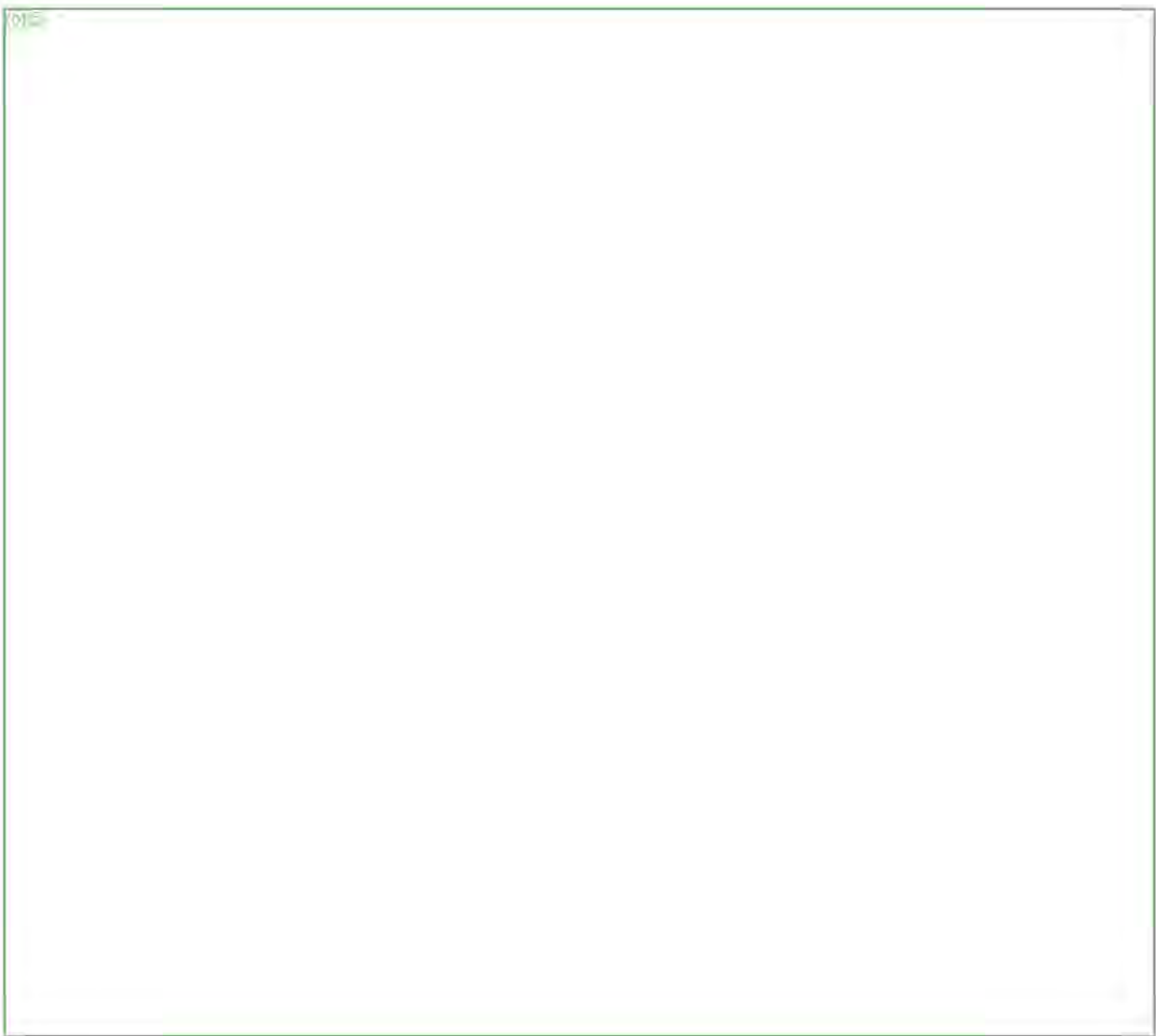
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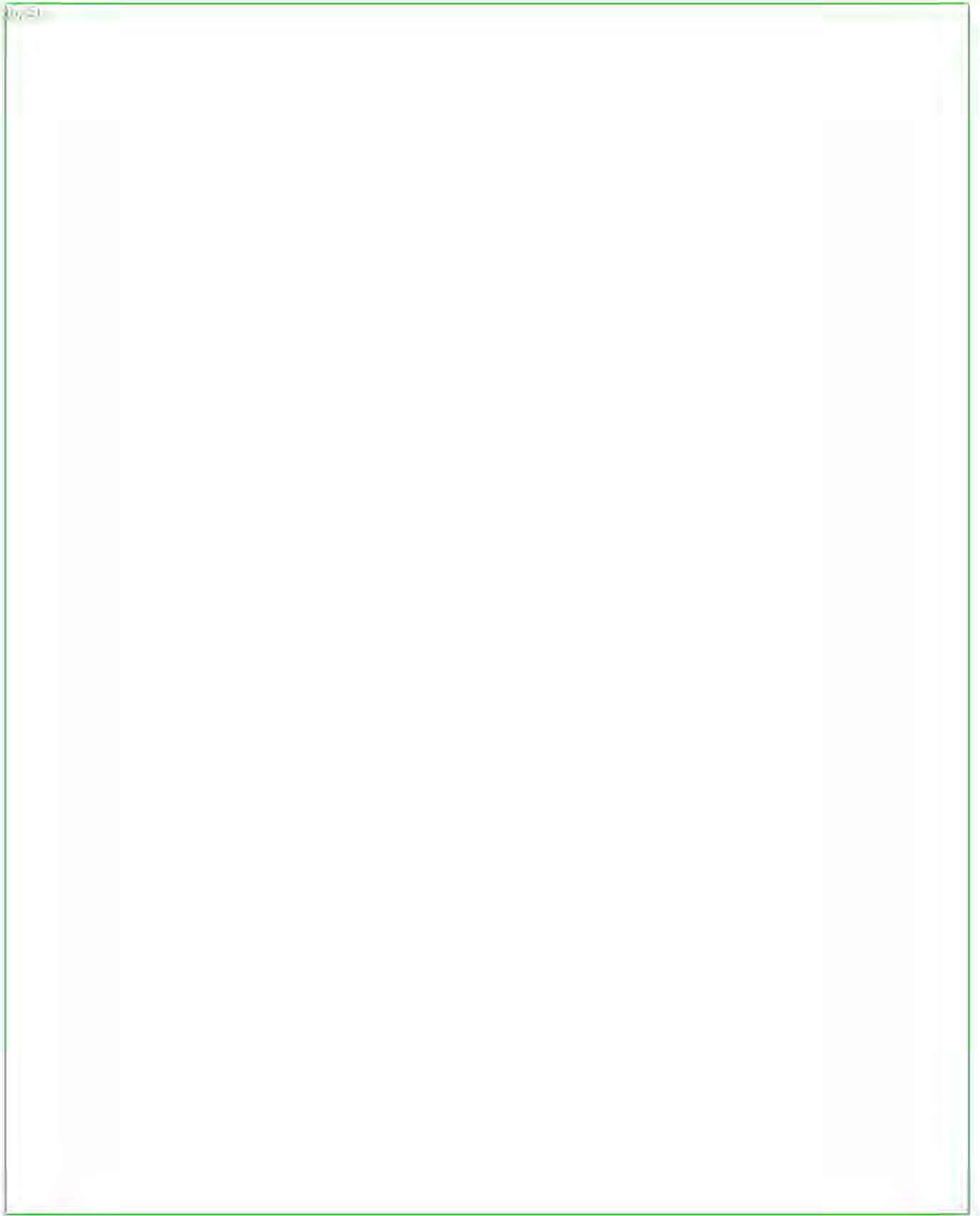
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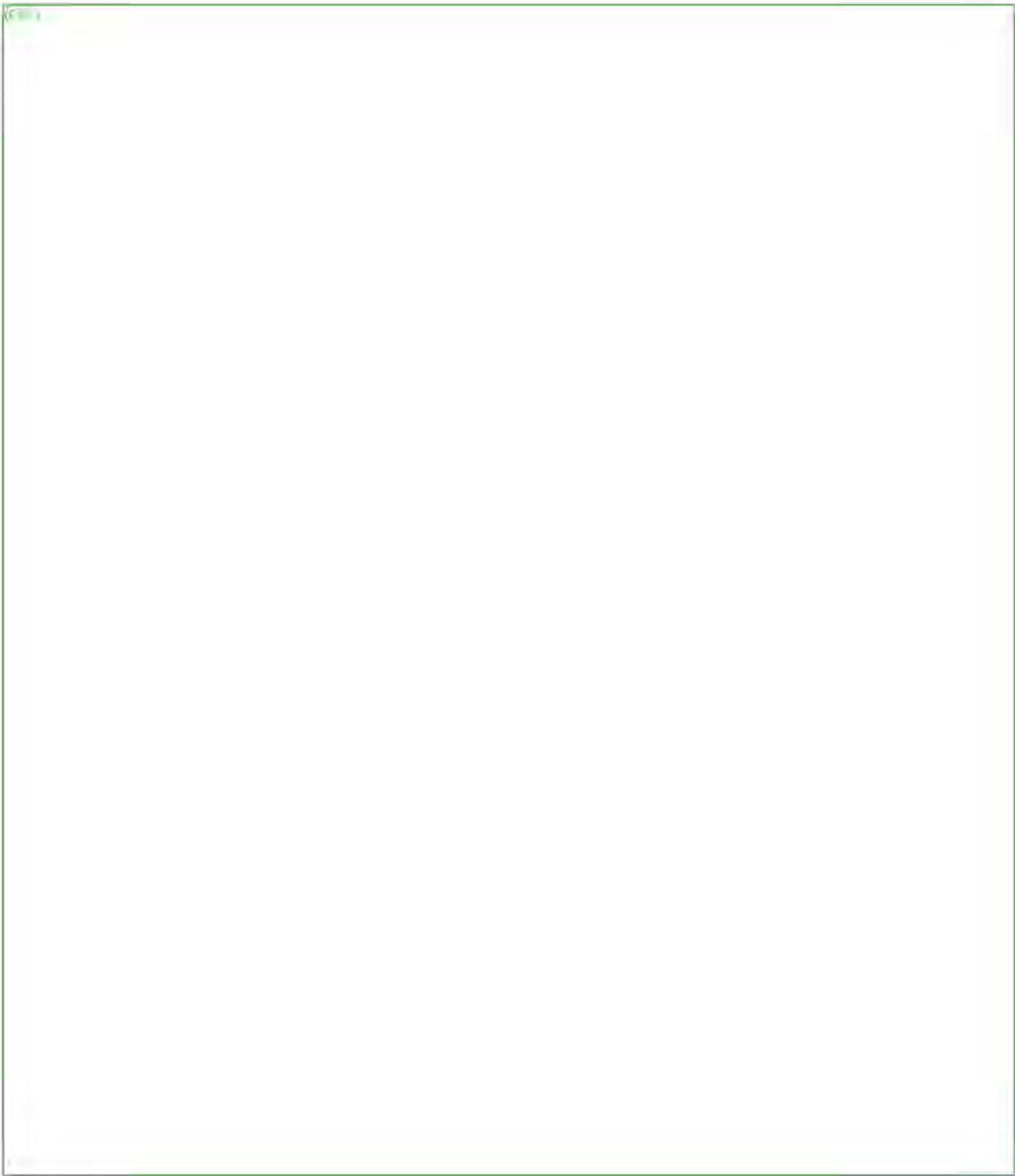








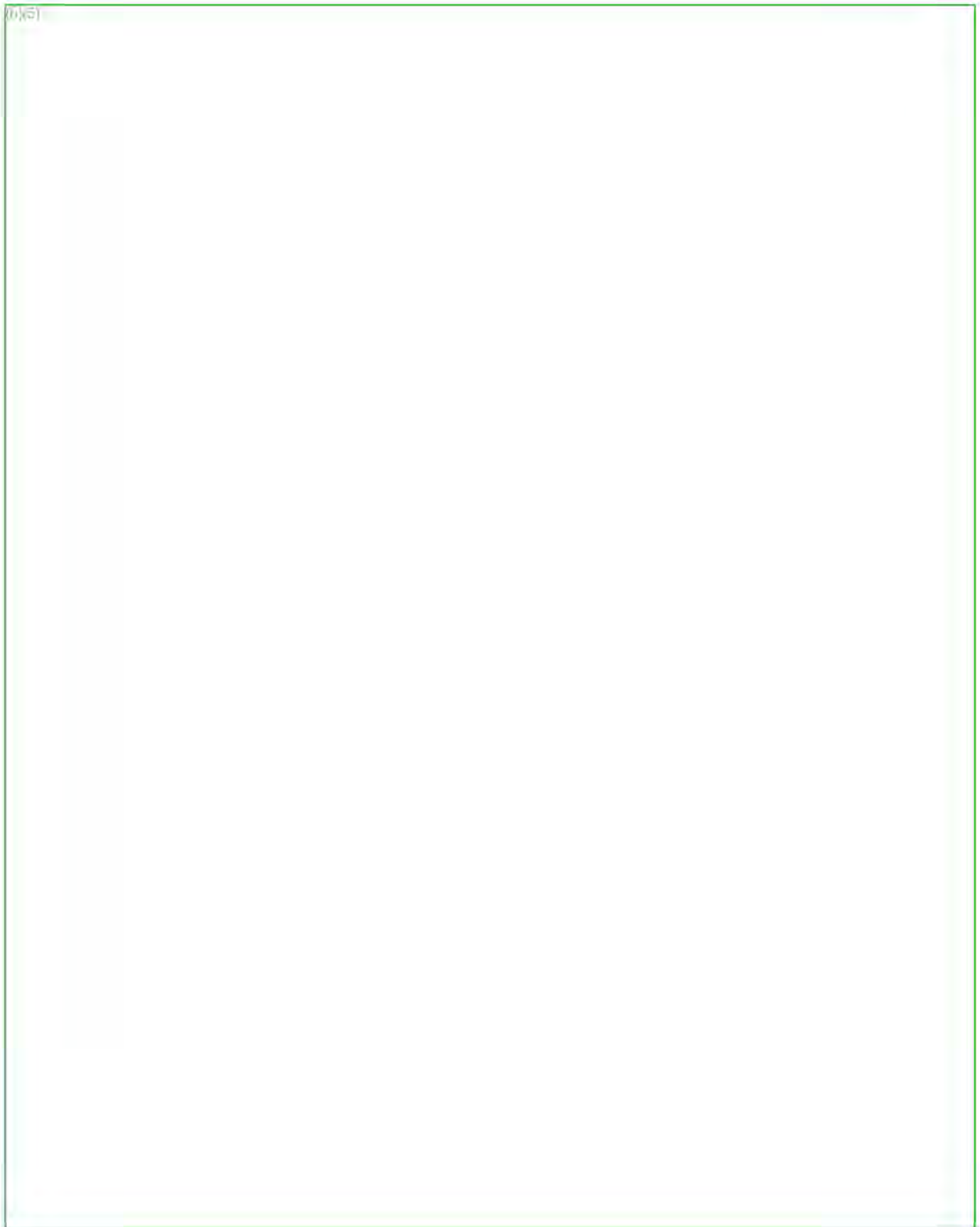






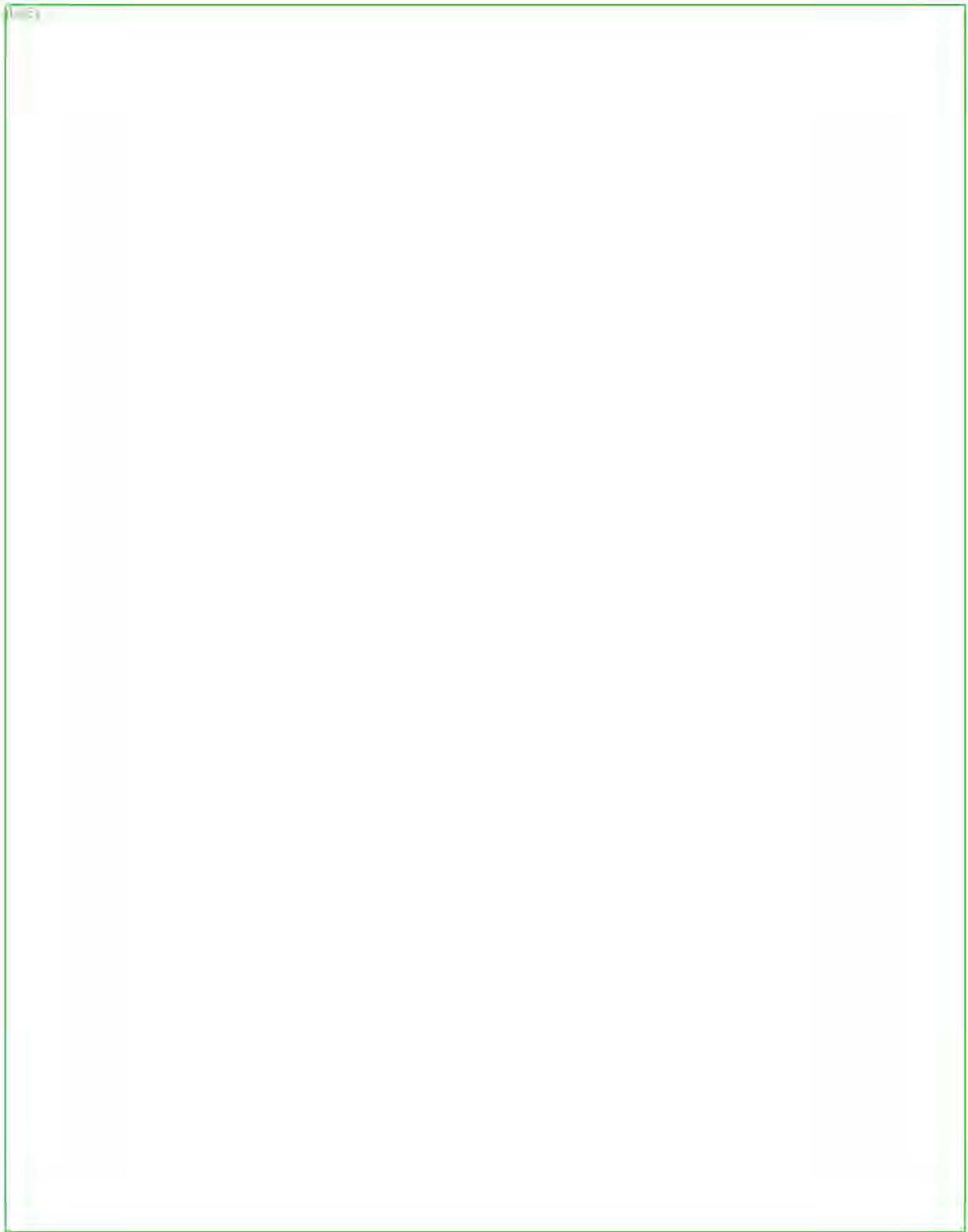
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